Supporting patients undertaking heart failure self-management using multi-stakeholder co-design of a mobile health application.

by

Leanna Sarah Woods

RN, BN (Hons), Grad.Cert.Nurs. (Cardiovascular)

Australasian College of Health Informatics Fellowship by Training candidate

School of Nursing

Submitted in fulfilment of the requirements for Doctor of Philosophy

University of Tasmania June 2019

Abstract

Heart failure is a prevalent, progressive chronic condition of considerable economic burden which places great strain on patients, family caregivers and health services. Self-management is supported by healthcare policy and is the mainstay for long-term heart failure care, however adherence to recommended guidelines is challenging with the existing literature reporting that patients are struggling to apply them to daily life.

The aim of this research was to explore how patients might be supported in heart failure self-management with a mobile health app co-designed by patients, family caregivers and clinicians.

Design Science Research Cycles, Design Thinking and co-design informed the research design. The Design Science Research Cycles framework focuses on a design that is relevant to the environment and consistent with the knowledge base. Design Thinking provided structure to the innovation process and co-design principles facilitated stakeholder interactions.

A four-phased study was conducted using a multi-stakeholder team of seven patients, four family caregivers and seven clinicians. The process was facilitated by the lead clinician researcher embedded in the health service as a cardiac clinical nurse specialist.

In Phase I stakeholder perspectives on heart failure self-management were explored prior to app design and development. Patient, family caregiver and clinician experiences and opinions were collected, analysed and visually represented as research outputs. Phase II involved the conceptual design and iterative development of the app. Patient personas were created from research outputs from Phase I, and these were used in two multi-stakeholder design workshops and two app wireframe feedback cycles. Next, in Phase III, the *Care4myHeart* app was tested in a 14-day usability study with a new subset of patients in the home setting to understand the patient user experience. Phase IV involved a process evaluation whereby experiences of those involved in the co-design process were explored.

This thesis is structured around and includes nine publications: seven articles have been peer-reviewed and published; one is in press; and one article is currently under review.

Key findings are reported in relation to each of the stakeholder groups involved in the research. For patients, daily self-management habits were established without the use of technology, so they were unsure how the app would fit in their current routines. Clinicians were easily-recruited, motivated research participants involved in each development stage and highly regarded the final app design. The lead clinician researcher led a highly structured Design Thinking process which

allowed efficient development of the app. Executing the nurse-led innovation project required strong leadership and commitment in a negotiation of competing priorities as a clinician, researcher and app developer. Additionally, discovering the art and science of design was found to be powerful for this research. In regard to stakeholder interactions, co-design methods helped negotiate tensions between stakeholders as the design unfolded, especially because clinicians were more involved than patients. Co-design methods also provided a format to account for power differences between the healthcare consumer and healthcare provider. Overall, stakeholder interactions were effectively managed.

Local mobile health app design can be achieved through partnering with patients, family caregivers and clinicians. This thesis contributes to the emerging body of knowledge on clinician-led context-specific apps, co-design processes and collaborative engagement with healthcare teams. There is appetite to engage more service users into healthcare improvement projects so further research is urgently needed to empower clinical teams to operationalise co-design in practice.

Statements and declarations

Declaration of Originality

This thesis contains no material which has been accepted for a degree or diploma by the University or any other institution, except by way of background information and duly acknowledged in the thesis, and to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgement is made in the text of the thesis, nor does the thesis contain any material that infringes copyright.

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The research associated with this thesis abides by the international and Australian codes on human and animal experimentation, the guidelines by the Australian Government's Office of the Gene Technology Regulator and the rulings of the Safety, Ethics and Institutional Biosafety Committees of the University.

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Statement of Co-authorship

The contributions to authorship of publications contained in this thesis is outlined.

Key: Authors

LW: Leanna Woods

EC: Elizabeth Cummings

JD: Jed Duff

ER: Erin Roehrer

KW: Kim Walker

N/A: Not applicable

The order in the following table is LW as primary author, then co-authors are listed alphabetically.

Publication number	**Conception & design of the research project**	Data collection	**Analysis & interpretation of research data**	**Writing/drafting**	Overall responsibility
1	LW, EC, JD, KW	LW	LW, EC, JD, KW	LW, EC, JD, KW	LW
2	LW, EC, JD, KW	N/A	N/A	LW, EC, JD, KW	LW
3	LW, EC, JD, KW	LW	LW	LW, EC, JD, ER, KW	LW
4	LW, EC, JD, KW	LW	LW	LW, EC, JD, KW	LW
5	LW, EC, JD, KW	LW	LW	LW, EC, JD, KW	LW
6	LW, EC, JD, KW	LW	LW	LW, EC, JD, KW	LW
7	LW, EC, JD, KW	LW	LW	LW, EC, JD, ER, KW	LW
8	LW, EC, JD, KW	LW	LW, EC, JD, ER	LW, EC, JD, ER, KW	LW
9	LW, EC, JD, KW	LW	LW, EC, JD	LW, EC, JD, ER, KW	LW

The following people and institutions contributed to the publication of work undertaken as part of this thesis:

Candidate	Leanna Woods, School of Nursing
Author 1	Elizabeth Cummings, School of Nursing, University of Tasmania, primary supervisor
Author 2	Jed Duff, University of Newcastle, co-supervisor
Author 3	Kim Walker, School of Nursing, University of Tasmania, co-supervisor
Author 4	Erin Roehrer, School of Technology, Environments and Design, University of Tasmania, co-supervisor

Author details and their roles:

Paper 1

Woods, L., Duff, J., Cummings, E., & Walker, K. (2019, April 26). Evaluating the Development Processes of Consumer mHealth Interventions for Chronic Condition Self-management: A Scoping Review. *CIN: Computers, Informatics, Nursing,* vol. published ahead of print, issue p. doi:10.1097/cin.0000000000000528 The publication is available at CIN through https://journals.lww.com/cinjournal/Abstract/publishahead/Evaluating_the_Development_Processes_of_Consumer.99433.aspx

Candidate was the primary author and contributed 65% of the planning, execution and preparation of the research project and subsequent paper. Author 1 contributed 5%, author 2 contributed 20% and author 3 contributed 10% to analysis & interpretation of research data and contributed to critically revising the paper.

Paper 2

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Candidate contributed approximately 70% to the planning, execution and preparation of the work for the paper. Author 1 contributed 20%, author 2 contributed 5% and author 3 contributed 5% to conception & design of the research project and critically revising the paper.

Paper 3

Woods, L., Duff, J., Roehrer, E., Walker, K., & Cummings, E. (2019). Representing the patient experience of heart failure through empathy, journey and stakeholder mapping. *Patient Experience Journal*, *6*(1), 55-62. The publication is available at https://pxjournal.org/journal/vol6/iss1/8/

Candidate was the primary author and contributed 80% of the planning, execution and preparation of the research project and subsequent paper. Authors 1, 2 and 3 contributed to the conception & design of the research project and authors 1, 2, 3 and 4 contributed to critically revising the paper. Overall, author 1 contributed 5%, author 2 contributed 5%, author 3 contributed 5%, and author 4 contributed 5%.

Paper 4

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Candidate was the primary author and contributed 80% of the planning, execution and preparation of the research project and subsequent paper. Author 1 contributed 10%, author 2 contributed 5%, and author 3 contributed 5% to conception & design of the research project and critically revising the paper.

Paper 5

L. Woods, J. Duff, E. Cummings and K. Walker. 2017. The development and use of personas in a user-centred mHealth design project. In *Proceedings of the 29th Australian Conference on Human Computer Interaction (OzCHI '17)*, Nov 28- Dec 1, Brisbane, QLD, Australia, Alessandro Soro, Dhaval Vyas, Bernd Ploderer, Ann Morrison, Jenny Waycott, and Margot Brereton (Eds.). ACM, New York, NY, USA, 560-565. The publication is available at the ACM Digital Library through https://doi.org/10.1145/3152771.3156186

Candidate was the primary author and contributed 85% of the planning, execution and preparation of the research project and subsequent paper. Author 1 contributed 5%, author 2 contributed 5%, and author 3 contributed 5% to conception & design of the research project and critically revising the paper.

Paper 6

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Candidate contributed approximately 70% to the planning, execution and preparation of the work for the paper. Author 1 contributed 20%, author 2 contributed 5%, and author 3 contributed 5% to conception & design of the research project and critically revising the paper.

Paper 7

Woods, L., Duff, J., Roehrer, E., Walker, K., & Cummings, E. Design of a Consumer Mobile Health App for Heart Failure: Findings from the Nurse-Led Co-Design of *Care4myHeart*. (Submitted manuscript, JMIR Nursing)

Candidate contributed approximately 60% to the planning, execution and preparation of the work for the paper. Author 1 contributed 15%, author 2 contributed 10%, author 3 contributed 5%, and author 4 contributed 10% to conception & design of the research project and critically revising the paper.

Paper 8

Woods, L.S., Duff, J., Roehrer, E., Walker, K., & Cummings, E. (2019). Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study. *JMIR Human Factors*, *6*(2), e13009. doi:10.2196/13009 Published and reproduced under the terms of Creative Commons Attribution licence 4.0. The publication is available at JMIR Human Factors through http://humanfactors.jmir.org/2019/2/e13009/

Candidate was the primary author and contributed 60% of the planning, execution and preparation of the research project and subsequent paper. Authors 1, 2 and 3 contributed to the conception & design of the research project. Authors 1, 2 and 4 contributed to analysis & interpretation of research data and authors 1, 2, 3 and 4 contributed to critically revising the paper. Overall, author 1 contributed 15%, author 2 contributed 10%, author 3 contributed 5%, and author 4 contributed 10%.

Paper 9

Woods, L., Roehrer, E., Duff, J., Walker, K., & Cummings, E., Co-Design of a Mobile Health App for Heart Failure: Perspectives from the Team, *Studies in Health Technology and Informatics* (In press, IOS Press).

Candidate was the primary author and contributed 65% of the planning, execution and preparation of the research project and subsequent paper. Authors 1, 2 and 3 contributed to the conception & design of the research project. Authors 1 and 2 contributed to analysis & interpretation of research data and authors 1, 2, 3 and 4 contributed to critically revising the paper. Overall, author 1 contributed 20%, author 2 contributed 5%, author 3 contributed 5%, and author 4 contributed 5%.

We the undersigned agree with the above stated “proportion of work undertaken” for each of the above published (or submitted) peer-reviewed manuscripts contributing to this thesis:

Signed Leanna Woods	Candidate	
Elizabeth Cummings	Author 1	
Jed Duff	Author 2	
Kim Walker	Author 3	
Erin Roehrer	Author 4	

Head of School Declaration

We the undersigned agree with the above stated “proportion of work undertaken” for each of the above published (or submitted) peer-reviewed manuscripts contributing to this thesis:

Signed

_____

Prof. Steve Campbell (Associate Head, Research)

For the Head of School

School of Nursing

University of Tasmania

Acknowledgments

Undertaking a PhD is a daunting, challenging and exciting adventure. There are many people who I would like to thank because I have no doubt that without their help I would not be submitting this thesis.

I would like to express my immense gratitude to my doctoral supervisors Dr Elizabeth Cummings, Associate Professor Jed Duff, Dr Kim Walker and Dr Erin Roehrer. My supervisors have been more helpful and encouraging that I could have dreamed for. I wish to thank them as supporters of my research, advocates for advancing healthcare and I wish to acknowledge them as co-authors in the publications in this thesis.

To my husband Paul for encouraging me to apply for my PhD and motivating me towards excellence. To our 7-year old son Hugo who is the joy in my life and a welcome distraction who effortlessly reorientates me back to reality after being enthralled in my thesis all day.

I appreciate the love and support from all members of my family, especially my mum Cathie Jennings, thank you for your unwavering support, practical assistance and confidence in my ability. To my best friend and nursing colleague Georgie Wenzel who supports and encourages me during the important points in my life.

I would like to recognise the invaluable input from a few special colleagues Carolyn Yeh, Paula Mohacsi, the St Vincent's Hospital Library staff and Carol Harding. Carol was my Design Thinking trainer and mentor. Thank you for sharing your vision and enthusiasm to design a better world through radical collaboration, creative ideation and inclusion. I know I will use Design Thinking in my personal and professional life far beyond this PhD. Thanks to my partner in research Kelly Edwards for your encouragement and company over the past 5 years.

To my clinical colleagues on Level 6 and St Vincent's Private more broadly, particularly my nurse manager Tracey Anderson, second-in-charge Simone Senior, Nurse Educators Emily, Sam and Paru and former Director of Nursing Jose Aguilera. To Amy Tai, thank you for our weekly tea breaks (and dinner if we could manage it!).

Through research travel to Hong Kong, Stockholm, Dublin and also within Australia I have met some amazing people including the EIT Health Summer School cohort, especially Christiane Gruenloh, I hope our friendship lasts for many years to come.

Research cannot be done without a community of peer reviewers and professional networks working together to advance academia. I wish to thank the anonymous referees from the journals

who have reviewed the manuscripts contained within this thesis. Further, thanks to the ACHI and HISA communities for their contributions to advancing health informatics research and career development of emerging researchers through the Fellowship by Training program.

The research conducted for this doctoral thesis would not have been possible without the financial contributions from affiliated organisations. Specifically, I wish to acknowledge the contributions made by: the St Vincent's Clinic Foundation, Sydney; The District Nurses, Hobart; the Research Training Program funded by the Australian Government; the University of Tasmania and the School of Nursing (formerly School of Health Sciences); and Andreas Wulf from Wulfsoft for providing a free license of PowerMockup (www.powermockup.com). A highlight of my research training program was attendance at the Summer School on User-centred Design of eHealth and mHealth Systems, and I wish to thank the European Institute of Innovation and Technology (Health) for funding my participation through a bursary.

Finally, and most importantly to the patients, family caregivers and clinicians who volunteered to participate in this research, thank you for your valuable contribution.

Glossary

Superscript[a] Application name pseudonym used to represent the names of apps which were not disclosed in articles included in the scoping literature review publication (Publication 1).

Adherence The extent to which a person's behaviour (for example taking medications and making dietary and lifestyle changes) corresponds with agreed recommendations from a health care professional (World Health Organization, 2003).

Affinity diagram A tool to organise many ideas into groups with common themes or relationships, used to help tame complexity and understand what is most important from ambiguous data (Weprin, 2016).

Application (app) A self-contained program or piece of software on a mobile device designed for a specific purpose (Moumtzoglou, 2016).

Co-design Design-led process incorporating creative and participative principles and tools to actively involve a diverse group of stakeholders to explore, develop and test solutions to shared challenges (Blomkamp, 2018a). It is participatory and collaborative, hence why it is also known as participatory co-design or collaborative design. In healthcare, co-design refers to the partnership of consumers, carers, families and healthcare workers to improve health services (Dawda & Knight, 2018).

Co-design workshops Multi-stakeholder sessions conducted on the hospital campus where design activities took place. Also referred to as design workshops and participatory design workshops.

Consumer mHealth intervention/application Software on a personal mobile device used for health or wellness.

Design artefact Material objects that can be viewed by others, used to challenge perceptions and inspire new ideas (Lupton, 2018). In this research, design artefacts included a journey map, stakeholder map, current care summary, clinical relevance information and personas.

Design brief Visual representation of design goals and implications on a poster.

Design Science Research Cycles A three cycle framework proposed by Hevner (2007) which applies design science to IT systems. The framework has a relevance cycle and rigor cycle which informs the design cycle, where a new design is created and evaluated.

Design sprint A collection of design activities conducted over a structured five-day period, where the team moves from idea to prototype to decision (Knapp, Zeratsky, & Kowitz, 2016).

Design Thinking A systematic innovation process that prioritises deep empathy for end-user needs and challenges to fully understand a problem in order to then develop a comprehensive, effective and technically viable solution (Roberts, Fisher, Trowbridge, & Bent, 2016).

Design Thinking Process A five phase innovation process which may be fluid or linear depending on the progression of the design: empathise with the end-user; define the problem; ideate a solution; prototype by building a solution; and test with the end-user (Hasso Plattner Institute of Design at Stanford University, 2017).

Electronic health 'A large array of information technology products and systems, each involved in some way with the gathering, integration, interpretation and communication of data and information' (Georgiou & Prgomet, 2019, p. 59) in health and healthcare.

Empathy/empathic approach Empathy involves developing 'a rich understanding of people's experiences, dreams, expectations, and life contexts' and is achieved through a meaningful emotional encounter between researcher and participant using dialogue (Wright & McCarthy, 2008, pp. 537-538).

Empathy map A Design Thinking and market research technique to represent subjective and objective qualitative information containing detail and verbatim quotes taken during participant interviews. It comprises four quadrants to represent what was said, what the participant was thinking, what they do and how they feel. Data collection and data analysis processes associated with empathy map use in this research were modified from Ferreira (2015) and Dam and Siang (2018).

Idea Matrix An ideation technique used in design workshops to generate a multitude of possible solutions to user problems, using post-it notes and a grid drawn on a whiteboard.

Insights Interesting or surprising realisations uncovered via an empathic approach to interviews.

Journey map A diagram that illustrates the steps on how customers interact with a product or service (Richardson, 2010).

Lightning Demos A design sprint activity adapted from Knapp et al. (2016) and used in this research whereby other smartphone apps are analysed and discussed.

Mobile Application Rating Scale (MARS) A 23-item scale as a multidimensional measure of the four objective app quality indicators (engagement, functionality, aesthetics and information) in addition to a subjective quality scale and supplementary modifiable 'app specific' section (Stoyanov et al., 2015). A user version of the scale (**uMARS**) is available (Stoyanov, Hides, Kavanagh, & Wilson, 2016).

Mobile health 'The use of mobile computing and communication technologies in health care and public health' (Free et al., 2010, p. 1).

Needs Verbs which relate to activities or desires, elicited from empathy map content and participant interviews.

Patient-centred care Focus on the person as active in his or her healthcare and central to the decision-making process (Ekman et al., 2011).

Patient-facing Software where the intended user is targeted, in this research the target user is a person with heart failure.

Persona Fictional characters based on research data, who represent potential users of a product or service (Nielsen, 2011).

Rose, Thorn, Bud technique A problem framing technique used in Design Thinking and human-centred design, as a method for analysing experiences, challenges and opportunities (Luma Institute, 2012). Red, blue and green coloured post-it notes are used to uncover positive, negative and improvement suggestions during the time of data collection, making it an efficient, versatile and effective approach (Luma Institute, 2012).

Self-management The daily, heart failure-specific activities conducted by an individual to maintain health and wellness. A discussion of the use of the terms self-management and self-care is provided in the terminology section (section 1.6).

Solution sketch A design sprint activity adapted from Knapp et al. (2016) whereby potential solutions to identified user challenges are drawn on paper.

Stakeholder map Visual representation of other persons involved, in this context, personal and professional stakeholders involved in heart failure self-management.

Storyboard A frame-by-frame comic-like representation of a prototype being developed on a whiteboard (Knapp et al., 2016), in this context, representing the main features and functions of the application interface.

Wireframes A visual, interactive (clickable) representation of app screens on a laptop computer in order to conduct design iterations. Hyperlinks represent the user experience of moving between screens. Also referred to as a low fidelity digital prototype.

Abbreviations

ACHI	Australasian College of Health Informatics
ACM	Association for Computing Machinery
AMICA	Autonomy Motivation & Individual Self-Management for COPD (Chronic Obstructive Pulmonary Disease) Application
App	Application
EBCD	Experience Based Co-design
eHealth	Electronic Health
GP	General practitioner
HF	Heart failure
JMIR	Journal of Medical Internet Research
MARS	Mobile Application Rating Scale
mERA	mHealth Evidence Reporting and Assessment
mHealth	Mobile Health
NCD	Non-communicable disease
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
uMARS	User version of the Mobile Application Rating Scale
WHO	World Health Organisation

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Chapter 1 : Introduction

This thesis with publications explores how patients might be supported in heart failure self-management with a mobile health (mHealth) application (app) co-designed by patients, family caregivers and clinicians. A pragmatic approach underpins the research where four phases were conducted to systematically address research objectives associated with the research question.

Chapter 1 provides an overview of the thesis. It describes the person-centred philosophy underpinning the research conducted, rather than a technocentric endeavour. It contains some general background to orient the reader to the local setting and context, plus it provides a rationale for the research conducted in this thesis.

The chapter is structured as follows:

Section 1.1 provides an explanation about the context of the research, with a particular focus on the influence clinical nursing has on the need to support patients in heart failure self-management;

Section 1.2 reports the healthcare challenge to be addressed by the research regarding the prevalence of heart failure and the challenges patients experience with condition self-management;

Section 1.3 discusses the research philosophy underpinning the research, particularly how person-centredness and pragmatism has influenced the action-orientated research conducted;

Section 1.4 discusses the research question to be explored and lists four research objectives including a description how they evolved;

Section 1.5 explains the setting of this practice-based research by describing the structure of heart failure care at the hospital campus; and

Section 1.6 summarises the structure of the thesis which is a thesis containing eight chapters and nine publications. Four research phases were conducted to address four research objectives. The section concludes with a description regarding the terminology used throughout this thesis.

1.1 Context

The clinical course of heart failure is marked by distressing symptoms, reduced quality of life, re-hospitalisations and early mortality (Burke, Jones, Ho, & Bekelman, 2014). This complexity provides an interesting and challenging context for nursing care. Nursing staff are able to develop a strong rapport with patients with heart failure because of the frequent readmissions and chronic nature of

the condition. Nurses may care for patients multiple times over many years, and are frequently exposed to the patient experience. At the beginning of hospital admission a patient may be hemodynamically unstable with severe shortness of breath and fluid overload, but with a week of medical and nursing care, they return to a stable health status and prepare for discharge. This pattern of severe, regular deterioration and hospitalisation followed by health optimisation in the discharge planning phase is familiar for patients and their families. In our healthcare environment where I work in a cardiac in-patient unit, nurses facilitate this process alongside other members of the multidisciplinary healthcare team. Nurses become a known and trusted professional on the ward in which patients and their families frequently attend, and this is an especially rewarding experience.

To further understand patient experiences of heart failure, I conducted a qualitative-descriptive study as part of my research honours degree in 2015 and published the results (Woods, Walker, & Duff, 2018). As with this PhD research, my honours research was conducted at the organisation in which I work, St Vincent's Private Hospital Sydney. The objective was to understand patients' experiences of fluid restriction self-management and identify factors affecting adherence. Participants reported that self-management was complex, tiring and challenging. Participants had limited skills to self-manage symptoms in their homes, many misunderstood the treatment rationale and participants were often confused about the benefits of adherence to fluid restrictions. These results confirmed international data that heart failure self-management is challenging, especially adhering to guideline requirements on a daily basis (Cameron, Worrall-Carter, Page, & Stewart, 2010; Dickson, Deatrick, & Riegel, 2008; van der Wal et al., 2006). The study concluded that more research was needed to improve adherence to daily guidelines for people with heart failure and provided the impetus to conduct the current doctoral research.

With the advancement of technology, it is inevitable that patients will see the possibilities of digitalising their healthcare to improving their health. In the developed world, smartphones are a resource tool for health information and healthcare delivery (Moumtzoglou, 2016). Patients are now storing medication lists on their smartphones, using various health applications and turning to the internet for medical information. Many of these options are portable, quickly accessible and freely-available which poses both opportunity and challenges. The research reported in this thesis explores the possibilities of mobile technologies to support patient empowerment and engagement of people living with the chronic, highly prevalent and complex syndrome heart failure.

1.2 The healthcare challenge

Heart failure affects at least 26 million people worldwide (Savarese & Lund, 2017) including more than 1 million Australians (ACI Cardiac Network, 2017) and it is expected to rise in prevalence (Savarese & Lund, 2017). The condition costs in excess of one billion dollars a year in Australia alone (National Heart Foundation of Australia, 2013).

Self-management is supported by healthcare policy (Anderson & Emmerton, 2016; Australian Health Ministers' Advisory Council, 2017) and is the mainstay for disease management in heart failure (Jaarsma, Cameron, Riegel, & Stromberg, 2017; National Heart Foundation of Australia, 2010). Self-management is linked to better quality of life, lower mortality and lower readmission rates (Jaarsma et al., 2017). Self-management involves the person monitoring their own health supported by their clinicians, with the aim to limit the worsening of symptoms by daily symptom monitoring and addressing deterioration promptly and effectively (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011). The National Heart Foundation of Australia evidence-based guidelines recommend daily out-patient self-monitoring (National Heart Foundation of Australia, 2013).

However, living with heart failure is viewed as a life changing event (Harkness, Spaling, Currie, Strachan, & Clark, 2015), and the experience is expressed as being very challenging (Clark et al., 2014). The literature reports the uncertainty patients experience applying heart failure recommendations and knowledge to the context of their daily lives (Strachan, Currie, Harkness, Spaling, & Clark, 2014). The challenging practice of self-care is a multidimensional system of many intersecting factors (World Health Organization, 2003), which, when conducted ineffectively, often fall to a suboptimal level to maintain adequate quality of life and avoidance of unnecessary hospitalisations (National Heart Foundation of Australia, 2008-2012, 2013; Sethares, Sosa, Fisher, & Riegel, 2014). Consequently, nearly half of all patients initially hospitalised with heart failure are readmitted within 3 to 6 months (National Heart Foundation of Australia, 2013).

Therefore, supporting patients and caregivers in long-term care is essential (Ponikowski et al., 2014). Specific challenges include teaching self-management skills relevant to the local healthcare context, patient socio-demographic population and the existing evidence-based guidelines already in place. A more detailed understanding of the literature is provided in Chapter 2 (section 2.1) where heart failure and self-management are explored in more detail.

1.3 Research philosophy

Academic research is guided by ontology (the study of existence) and epistemology (the theoretical study of knowledge) (Schneider & Whitehead, 2013). This research focuses on the health and disease experiences of patients with heart failure which aligns with the rich tradition of nursing research. Generally, nurse researchers seek a deep understanding of what it is to be human, and what it is like to be an ill human (Lawler, 1998). Philosophical beliefs about the individual's response to disease, treatment and recovery is part of the role of any healthcare professional (Schneider & Whitehead, 2013). But nurses specifically, as practitioners and people, are interested in how health and disease disrupt lives and the meanings patients give to this disruption because without this understanding nurses have a restricted capacity to help (Lawler, 1998). Research topics chosen by nurses frequently evolve from how clinical practice has moulded the way they come to know about the world (Lawler, 1998). Hence, the research reported in this thesis focuses on the human experience of heart failure from a variety of stakeholder perspectives. Additionally, the research methods and the findings are person-centred.

This research is action-oriented with the aim to work together collaboratively to support heart failure self-management. This aligns with pragmatism where the focus is on impacting the world, rather than simply understanding it (Goldkuhl, 2012). Goldkuhl explains that 'pragmatism has an interest not only for what 'is', but also for what 'might be'; an orientation towards a prospective, not yet realized world' (Goldkuhl, 2012, p. 140). Pragmatism can be appropriately applied to action research and design research (Goldkuhl, 2012) and is the most appropriate paradigm for this research.

Involving patients and families in this research was an essential approach. The action-orientation of pragmatism infers 'insider' research (Schneider & Whitehead, 2013) with an emphasis on service improvement to bring about change (Gerrish, Lathlean, & Cormack, 2015). Pragmatism involves action, change and the interplay between knowledge and action (Goldkuhl, 2012). There is clear interaction between researcher and research participants whereby meaning is co-produced *during* data generation (Goldkuhl, 2012). Similar to how highly practical clinical nursing is (Lawler, 1998), action research enlists a cyclical research process where actions are monitored, analysed and evaluated (Schneider & Whitehead, 2013). The approach involves real people and real problems (Schneider & Whitehead, 2013) with new knowledge emerging from the process (Schneider & Whitehead, 2013). Participatory action research refers to approaches that seek to empower patients, carers and other service users (Gerrish et al., 2015). This approach stresses the importance

of the active engagement of participants through democratic and reformatory processes (Schneider & Whitehead, 2013). Key drivers in the movement towards engaging users are consumerism, human rights, democracy and beneficence (Gerrish et al., 2015). As learnings evolve with the process, the researcher needs to respond to others, adopt a diverse range of research methods and adapt accordingly.

The philosophical underpinnings that exist in this research is based on the paradigms explained above. They are as follows:

1. The healthcare problem/challenge is subjective where meanings and perspectives of persons evolve through experiences;
2. People that are most impacted by the problem (patients and clinicians in a health service) are best positioned to bring about meaningful change; and
3. The solution is currently unknown but collaborative methods and methodological approaches can get us to the solution together.

A detailed description of the chosen methodological approaches which were informed by the research philosophy are detailed in Chapter 3 Research methods. In summary, these were: the Design Science Research Cycles; Design Thinking; and co-design. The Design Science Research Cycles framework focuses on a design that is relevant to the environment and consistent with the knowledge base. Design Thinking provided a staged approach to the innovation process and co-design principles facilitated stakeholder interactions.

1.4 Research question and research objectives

In this section, the research question and research objectives are listed followed by an explanation of how they evolved. As this research is collaborative and active, the research objectives were based on engagement with local stakeholders including patient, families and clinicians, together with a greater understanding of the domain of mHealth design conducted through the literature review. Overall, the research approach was person-centred rather than focused on technology.

The research question that was explored in this thesis was as follows:

Research question

How might patients be supported in heart failure self-management with a mobile health app co-designed by patients, family caregivers and clinicians?

To comprehensively explore the research question, four interrelated research objectives were identified. The four research objectives were:

Research Objectives

1. To explore stakeholder perspectives on heart failure self-management prior to app design and development.
2. To collaboratively design and iteratively develop a mobile health app with patients, family caregivers and clinicians.
3. To understand the patient experience using the app for heart failure self-management.
4. To evaluate the multi-stakeholder co-design process.

Research question development

Consistent with the person-centred approach to the research, the research question and research objectives evolved from the people involved. Initially, a plan for this doctoral nursing research was drafted to address the healthcare challenge associated with heart failure (section 1.2). Specific goals were to improve patient symptom self-management and assist with adherence to evidenced-based guideline requirements to improve clinical outcomes, enhance patient self-efficacy and subsequent satisfaction with their disease management. We began to plan for an intervention (or collection of interventions) to increase adherence to self-management guidelines in heart failure.

Conversations and observations continued throughout this planning and drafting phase. Dialogue with people impacted by heart failure uncovered some realisations. Some of these initial interactions revealed that, more than ever before in clinical practice, patients were beginning to use technology for their health and safety. On admission, patients or family members displayed digital copies of their medication lists on their smart devices. Some streamed music to assist with anxiety or podcasts for loneliness. Another patient recalled his blood pressure history on a smartphone app, demonstrating his awareness of the clinical deterioration which contributed to his hospital admission. Second, informal conversations with clinical colleagues in the corridors of the hospital (most of whom were cardiac nurses and cardiologists) uncovered that they would be interested in a smartphone app for the purpose of heart failure education and monitoring. Third, the healthcare climate was trending towards innovative, often digital, solutions to complex healthcare problems. It was becoming evident that consumer technologies in healthcare were evolving at a much slower pace than in other sectors. As a result, the research question was established. The research question was based on the premise that an appropriately tailored app which encourages and facilitates

patient engagement and empowerment in the self-management of their heart failure, and developed in consultation with patients and clinicians, could improve the patient experience of heart failure.

An examination of the literature was needed to see if it was possible for a clinician to lead the development of a mHealth app. The scoping literature review (Publication 1, section 2.3) enabled a deeper understanding of the research domain of mHealth app design in the context of chronic condition self-management. The literature review question was: *How are mobile health apps for chronic condition self-management developed?* This understanding deepened in the data analysis phase where development teams and development processes were identified. Answering this literature review question resulted in two realisations. First, the development process needed to be structured and borrowed from other domains like design and innovation. Second, effective ways to involve and engage stakeholders were needed to address the research question. Informed by these realisations and the research philosophy, the research objectives were finalised.

It was important to understand existing mHealth apps for heart failure. Contact with the research division of the National Heart Foundation of Australia in February 2016 confirmed that they were not funding research specifically related to a self-management app for heart failure. A search of the commercial app stores yielded only a few, low-quality apps to record blood pressure, weight and medications. Apps were not condition specific, nor do they feature the Australian guidelines for the daily monitoring of heart failure as recommended by the National Heart Foundation of Australia. Conversations with clinical colleagues confirmed that no heart failure support app was recommended by the heart failure service at the hospital.

The methodological approach and study procedures used to address the research objectives are detailed in Chapter 3 where the research methods are presented.

1.5 Setting

St Vincent's Hospital Campus, Sydney was chosen as the site for this research. As a clinical nurse embedded in the health service providing direct care, I understood the context. My role within the health service during the time of the research was clinical nurse specialist (cardiology), St Vincent's Private Hospital Sydney.

St Vincent's Hospital Campus is a tertiary hospital campus located in inner Sydney, Australia. Historically, the campus has been a leader in cardiac research in part due to the pioneering cardiac surgeon Dr Victor Chang. In honour of his contributions to cardiology in Australia and worldwide, a

research institute in his name is located on the hospital campus. St Vincent's continues to contribute to cardiac care, both clinically and through medical research. It has a well established reputation for providing specialised cardiac care and is the only facility to perform cardiac transplantation in the Australian state of New South Wales.

Patients have access to the heart failure service across the hospital campus regardless of health funding. The nurse-led heart failure service is provided free of cost by Medicare (publicly funded universal healthcare in Australia), providing ongoing education and support for newly diagnosed and existing patients, including linking patients to other health or social care services in the community. For acute care, private in-patient care is provided at St Vincent's Private Hospital Sydney and public in-patient care is provided by St Vincent's Hospital Sydney. St Vincent's Clinic is the medical out-patient department of the St Vincent's Hospitals, offering specialised medical, radiology and pathology services.

For people with heart failure in the local population, current practice involves out-patient heart failure care planning, periodic appointments with a specialist heart failure nurse and/or a cardiologist, routine heart health tests and then if required, hospitalisation during acute exacerbations. Written literature, disseminated from the National Heart Foundation of Australia to local patients, includes the heart failure pamphlet 'Living well with Heart Failure' and the 'Action Plan' flowchart (National Heart Foundation of Australia, 2008-2012). This resource offers dot-point guidelines together with strategies and tips to encourage self-management in the home setting and information about appropriate care-seeking.

1.6 Structure of the thesis

This thesis is structured around and includes nine publications: seven articles have been peer-reviewed and published; one is in press; and one article is currently under review. Approval to use publications in this thesis is provided in Appendix A. Each publication is included in the format, style and layout of the corresponding journal. For example, American spelling (for example, esthetics and edema in place of aesthetics and oedema) and grammatical style (for example, Oxford comma use) was used in publications to be consistent with publication requirements specific to the journal. The use of the collective first person was appropriate for publications reporting the research as an industry project. References associated with publications are included in each publication's reference list, rather than at the end of the thesis. For differentiation, only references used in the thesis not associated with a publication are contained in the thesis reference list.

Four phases of research were conducted to address four research objectives. A summary of the thesis structure is presented in Table 1 and explained thereafter.

TABLE 1. STRUCTURE OF THE THESIS

Chapter	Research objective	Publication number
1 Introduction		
2 Understanding the literature		1
3 Research methods		2
4 Phase I. Stakeholder perspectives prior to app design and development	1	3, 4
5 Phase II. Collaborative design and iterative development	2	5, 6
6 Phase III. Usability test with patients	3	7, 8
7 Phase IV. Process evaluation	4	9
8 Discussion and conclusion		

This introduction chapter (**Chapter 1**) has provided a description of the research context, healthcare challenge, research philosophy, setting, the research question and the research objectives.

Chapter 2 contains a discussion of the existing literature. The first section of Chapter 2 involves a limited descriptive literature review on the main topics of this research: heart failure; self-management; and mobile health. The second section of the chapter presents a focused scoping review on the development processes of self-management consumer apps (Publication 1).

Chapter 3 presents the research methods undertaken for this thesis. Four research phases were conducted to address the research objectives. The chapter contains Publication 2 which summarises the research methodology with further detail provided to complement the contents of the publication. The methodological approach is described in detail and the study procedures outlined. The chapter closes with a discussion of the ethical considerations in this research.

Chapter 4 presents research Phase I where stakeholder perspectives on heart failure self-management were explored prior to the design and development of the app. Phase I findings are reported per stakeholder group. First, the patient and family caregiver experience of heart failure is presented in Publication 3, then the clinician experience is presented in Publication 4. The chapter summation lists the design outcomes from Phase I including the importance of meaningfully representing stakeholder perspectives in preparation for Phase II.

Chapter 5 reports Phase II where the processes used to design and develop the app are described. In Publication 5 the use of patient 'personas' is explained in detail, followed by the systematic steps involved in the conceptual design and iterative development of the app (reported in Publication 6).

The chapter summation emphasises the importance of the pragmatic approach to the design in that the app was successfully built and released at the conclusion of Phase II.

Chapter 6 reports the findings from Phase III reporting the patient experience of using the developed app for heart failure self-management. The user interface of the app, named *Care4myHeart*, is presented (Publication 7) and then the findings from the usability study conducted with patients is presented (Publication 8).

Chapter 7 presents Phase IV of the research which involved an evaluation of the co-design process by those involved and their perspectives on the design outcome (Publication 9). The chapter concludes with a summation on participant perspectives and the rapid and flexible evaluation method.

Chapter 8 is the discussion and conclusion chapter. The chapter presents a discussion of the outcomes from the research phases explained in Chapters 4-7 and how they contribute to answering the research question in the context of the whole research. The format of Chapter 8 includes a discussion on the key findings associated with operationalising the clinician-led app development process within the hospital setting. Consistent with a person-centred research philosophy, findings are reported per stakeholder group involved. Research contributions, implications for clinician researchers, limitations and future directions are summarised.

Terminology

Clarification of the terminology used in this thesis is required as it is structured around and includes publications. Terminology varied over the course of the research as my knowledge grew and the field developed, which are reflected in the publications and highlighted in this section. The term **ethnographic interviews** initially used during research planning was later omitted due to the absence of this descriptor in the Design Thinking literature. The term **prototype** was initially used to represent the app to be developed, however this term was later omitted to represent that the final app was a functional, stable product for use.

The five phases of the Design Thinking Process are referred to as **stages** in this thesis to differentiate them from the four research **phases** conducted for this research. The term **Design Thinking** is predominantly capitalised in this thesis however capitalisation of this term remains inconsistent in the academic and grey literature, hence some publications keep the lower-case term. The research conducted for this thesis is also referred to as a ‘study’ or ‘project’. Progression of the development

for mobile health interventions in the scoping literature review (Publication 1, section 2.3) was classified as following:

- Predesign phase: before the formulation of the mobile health intervention;
- Initial design phase: developing the first version of the mobile health intervention; and
- Redesign phase: refinement and testing of the mobile health intervention.

In this thesis, **self-management** refers to the daily, heart failure-specific activities conducted by an individual to maintain health and wellness. This interpretation is aligned to the following definition of self-management in the context of chronic conditions:

> the process in which patients take responsibility and decision making for achieving disease control, health and well-being through a wild [sic] range of illness-related activities: recognizing symptoms, adhering to treatments, managing physical and psychosocial consequences and lifestyle changes due to their specific condition (Ausili, Masotto, Dall'Ora, Salvini, & Di Mauro, 2014, p. 182).

Although the term **self-care** is commonly reported in the academic literature on heart failure, it can be considered a more general term and preventative strategy. For example, Riegel, Jaarsma, and Strömberg (2012) refer to self-care as the maintenance of health through health promotion and illness management, and claim it is conducted in both healthy and illness states. Consequently, the term self-management was preferred and therefore adopted in the thesis. The exception to this is the use of the term self-care in Publication 3 (section 4.2). Self-care was used to be consistent with the three systematic reviews (Clark et al., 2014; Harkness et al., 2015; Spaling, Currie, Strachan, Harkness, & Clark, 2015) used in the discussion section and the terminology used by the journal.

An important change in terminology occurs between Chapter 4 and Chapter 5. From Chapter 5 onwards, the **visual representations** of experience data referred to in Chapter 4 begin to be referred to as **design artefacts**. There were three reasons for delaying the use of the term design artefact until Chapter 5. Firstly, as the readership of the publications in Chapter 4 are more likely in health domain rather than the design domain, visual representations was considered more fitting. Secondly, as a nurse discovering the art and science of design, the terminology was unfamiliar. The third reason was to focus on the content of the experience data itself, rather than report a perceivably-mechanical process of design. The term design artefact was avoided to remain consistent with the person-centred and experienced-focused qualitative inquiry reported in Chapter 4.

Participants in this research relate to patients, family caregivers and clinicians involved in co-design. The specific participants involved in each research phase is explicit in the thesis for clarity. Participants actively involved in the co-design process are also referred to as 'design team members' and 'co-design team members'. A discussion on clinicians as 'co-investigators' rather than research participants is provided in section 3.6 Ethical considerations.

Patients refer to people with heart failure who use the health service as an in-patient or out-patient. The term 'out-patients' was discontinued after publication 2 to avoid confusion, then 'patients' was consistently used. **Users** (or end-users) refer to patients with heart failure who may use a mobile health app for self-management.

Family caregivers refer to immediate family members of patients with heart failure who assist with self-management. The generic term 'carers' used in the ethics application was later changed to 'family caregiver' because all recruited carers in the study were family members of patients with heart failure (rather than an unrelated caregiver or friend). Further, family caregivers who were recruited in Phase I did not identify with the term 'carer' and saw their role as husband/wife/son/daughter.

Clinicians refer to members of the multidisciplinary team who provide care for patients with heart failure in the health service.

Lead clinician researcher refers to the doctoral student who conducted this research, also known as the lead researcher, project lead, clinician developer, local clinical nurse specialist and student researcher.

Chapter 2 : Understanding the literature

The focus of this chapter is to provide an overview of the relevant literature. As a thesis with publications, relevant literature is included within the body of each of the publications contained in this thesis. However, these literature synopses only relate to the content of the respective manuscripts corresponding to one segment of the research reported. Consequently, and to avoid repetition, this chapter provides an overview of heart failure as a condition, the concept of self-management and background on mHealth as a subset of eHealth. Additionally, this chapter presents a focused literature review on development processes of mHealth interventions for chronic conditions. The latter was a necessary step prior to planning for, and refining, the study procedures described in Chapter 3 in order to address the research question.

Chapter 2 is divided into the following sections:

Section 2.1 provides a limited descriptive review on the relevant topics: heart failure; self-management; and mobile health. This section provides a general background which will provide the uninitiated reader background information as it relates to the remainder of the thesis, noting that each publication includes the relevant literature;

Section 2.2 is the preface to Publication 1, a scoping review focused on development processes of consumer mobile health interventions for chronic condition self-management;

Section 2.3 presents Publication 1 - *Evaluating the Development Processes of Consumer mHealth Interventions for Chronic Condition Self-management: A Scoping Review* published with Computers, Informatics, Nursing journal in 2019; and

Section 2.4 provides a summation on Chapter 2 with regard to how the literature informed the methodological approach and study procedures reported in Chapter 3.

2.1 Background literature

Heart failure is a complex and symptom-laden condition of increasing prevalence and significant burden to patients, families and health services. Self-management relates to the enablement of people impacted by heart failure to address condition-related consequences in their daily life and is linked to empowerment and engagement of people to be at the centre of their own healthcare. Finally, the advancement of technology in the contemporary era has contributed to the expansion of

mHealth and background on this research domain is described. These three domains are explored in the following chapter sub-sections in a limited descriptive literature review.

Heart Failure

Heart failure is a complex progressive clinical syndrome of impaired ventricular function (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011). Risk factors include coronary artery disease, cardiomyopathy, hypertension and previous heart attack (National Heart Foundation of Australia, 2008-2012). Due to weakened heart contractions, patients with heart failure often experience symptoms related to fluid retention such as breathlessness, chest pain, abdominal distension and peripheral oedema (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011). These symptoms are experienced with or without physical activity depending on the level of progression of the condition. The disease trajectory for many patients demonstrates a turbulent and overall worsening symptom burden. In patients who present for hospitalisation due to their worsening symptoms, termed an 'acute exacerbation', nearly 80% experience three or more heart failure symptoms (Sethares et al., 2014). The five year survival rate of those diagnosed with heart failure is 50-75% (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011). The only cure for heart failure is cardiac transplantation.

Heart failure is, and will continue to be, a highly prevalent disease (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011). Although it has been a challenge to define specific numbers, it is expected to affect 1-2% of the Australian population (Sahle, Owen, Mutowo, Krum, & Reid, 2016). There is an increase in heart failure prevalence worldwide which can be attributed to the ageing population and advancement in treatments (Savarese & Lund, 2017). Further, the condition is more prevalent in some of the most disadvantaged groups in our community (National Heart Foundation of Australia, 2013). For example, Aboriginal and Torres Strait Islander people are more at risk and are more likely to die from heart failure than non-Indigenous Australians (National Heart Foundation of Australia, 2013). The elderly are more at risk. Heart failure is the most prevalent diagnosis of those aged over 65 years (Sethares et al., 2014), with a prevalence three or more times greater than that of the general population (Sahle et al., 2016). Heart failure is more prevalent in rural and remote regions in comparison to metropolitan areas and capital cities (Sahle et al., 2016). Further contributing to the incidence and prevalence in our community, the projected Australian population in 2056 is 40 million people, and a quarter of these (23-25%) will be aged 65 or older (National Heart Foundation of Australia, 2013).

As with other chronic diseases, the expense on the healthcare system is significant. In Australia, the condition costs in excess of one billion dollars a year with re-hospitalisation rates between 29% and 49% within 3-6 months post initial discharge (National Heart Foundation of Australia, 2013). Heart failure remains a major and growing public health problem across the globe (Savarese & Lund, 2017).

Self-management

While heart failure often shows an adverse trajectory towards morbidity and mortality, self-management is an important practice to improve patients' symptoms and quality of life. In chronic conditions, self-management refers to the process to maintain health, in which patients take responsibility and decision making for achieving disease control (Ausili et al., 2014). This involves managing many aspects of their condition like treatment adherence, recognising symptoms, making lifestyle changes and managing physical consequences (Ausili et al., 2014). As explained in the terminology section, self-management is used in the thesis rather than self-care to indicate the condition-specific requirements of heart failure, rather than a broad approach to wellness often associated with the term self-care.

In Australia, the evidence-based non-pharmacological heart failure guideline recommendations include the following (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011):

1. Regular physical activity, tailored to patient ability with recent evidence strongly supporting the benefit of regular physical activity;
2. Nutritional requirements, including a diet low in saturated fat, low in sodium and high in fibre. Small portion sizes, avoidance of undernutrition and obesity, and referral to a dietitian are recommended;
3. Fluid management, mostly restricted to 1.5 litres per day. Patients are supported to self-regulate their diuretic dose (medication to make the kidneys produce more urine in order to relieve heart failure-related congestion) based on daily weight monitoring and awareness of symptoms, although being aware of the risk of renal dysfunction and dehydration in warmer weather. Limits to caffeine and alcohol are also recommended;
4. Smoking cessation; and
5. Psychological support, including addressing depression and low mood, social isolation and lack of social supports.

Therefore, components of patient education regarding self-management include (National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand, 2011, p. 21):

- Developing a good overall understanding of the pathology and treatment;
- Adhering to prescribed pharmacological and non-pharmacological treatments;
- Monitoring their condition and adjusting treatment accordingly; and
- Seeking healthcare when signs and symptoms worsen.

Following heart failure guidelines through self-management can contribute to symptom control, unnecessary hospitalisations and improve quality of life (Jaarsma et al., 2017; National Heart Foundation of Australia, 2008-2012). Therefore, improving self-management through patient education and therapeutic collaboration with health care professionals is important (National Heart Foundation of Australia, 2008-2012). The literature supports the encouragement and availability of heart failure clinics (National Heart Foundation of Australia, 2008-2012) or other care models which provide specially trained health care professionals (National Heart Foundation of Australia, 2013) to improve support for self-management. The Clinical Service Framework for chronic heart failure (ACI Cardiac Network, 2017, p. 28), Standard 7, states that all patients with heart failure have access to continuing care by a multidisciplinary, coordinated, comprehensive heart failure management service including access to a rehabilitation program.

Adherence is 'the extent to which a person's behaviour – taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider' (World Health Organization, 2003, p. 3). As noted in the World Health Organization (2003) document, the term 'adherence' implies the patient's agreement to a mutually-decided treatment plan in collaboration with the patient's cardiologist and/or specialist heart failure nurse.

Self-management regimes, however, are complex and the experience of living with heart failure is expressed as being very challenging (Clark et al., 2014). The literature reports the uncertainty patients experience applying heart failure recommendations and knowledge to the context of their daily lives (Strachan et al., 2014). Self-management is a multidimensional system of many intersecting factors (World Health Organization, 2003), which when conducted ineffectively, often falls to a suboptimal level to maintain adequate quality of life and avoid hospitalisation (National Heart Foundation of Australia, 2008-2012, 2013; Sethares et al., 2014). The National Heart Foundation of Australia (National Heart Foundation of Australia, 2013, p. 14) identifies that some re-hospitalisations are 'preventable, and therefore avoidable' with optimal adherence.

The adherence challenges in heart failure are consistent with other chronic conditions, where adherence to long-term therapies generally is only approximately 50% (World Health Organization, 2003). Traditionally generalised as a 'patient problem', self-management is also impacted by other factors. More research is required to enable health care teams to help improve patient adherence. Persisting long-term with an optimal non-pharmacological treatment plan proves to be challenging for patients yet improvements in adherence are our best investment in chronic condition management (World Health Organization, 2003). This is especially significant in our ageing population as we strive to improve out-patient management of chronic conditions to decrease healthcare costs.

Importantly, family caregivers are frequently involved in the care of people with heart failure. As heart failure progresses, patients experience clinical decline (Strachan et al., 2014) in which the assistance from others becomes required. Caregivers can frequently detect subtle changes in the patient's condition as they are constantly observing the person with heart failure (Strachan et al., 2014) and have been found to view themselves as the primary care providers with the health system enabling that care with suggestions and recommendations (Burke et al., 2014).

Mobile health

Mobile health is a subset of eHealth. As described by Georgiou and Prgomet (2019, p. 59) eHealth 'encompasses a large array of information technology products and systems' whereas mHealth can be defined as 'the use of mobile computing and communication technologies in health care and public health' (Free et al., 2010, p. 1). mHealth takes place on a mobile device which refers to a portable computer or digital device, such as a mobile phone, tablet, notebook, watch or glasses (Moumtzoglou, 2016).

Rapid improvements in technology and the ubiquity of the internet have facilitated the advancement of mHealth. Globally, 95% of the worlds' population is serviced by mobile-cellular service (International Telecommunication Union, 2015). In Australia the uptake of internet and smartphone use is as common, if not more common than the United States of America. Internet users represent 82.3% of the Australian population (in the USA 81% and in the UK 87%) (World Health Organization, 2016). In 2015 mobile-cellular subscriptions calculate at 105.59% of the Australian population (World Health Organization, 2016). While mobile phone users are proportionately divided between gender, ethnicity, race and community settings (McNiel & McArthur, 2015), smartphone users are more likely to be younger, more highly educated and from a higher income household (Bailey et al., 2014).

There is growing interest in consumer mHealth to help with improving health and wellness, often in the form of an application. An app is a self-contained program or piece of software on a mobile device designed for a specific purpose (Moumtzoglou, 2016). The delivery of healthcare services via mHealth can assist with evaluating, diagnosing and treating patients (Moumtzoglou, 2016). For example, there is potential to support health education programs like cardiac rehabilitation, a structured evidenced-based secondary prevention program for patients post myocardial infarction. Improvements in uptake (80% vs 62%), adherence (94% vs 68%) and completion (80% vs 47%) were found in a randomised control trial using smartphone-based home-based cardiac rehabilitation program compared to the traditional cardiac rehabilitation program (Varnfield et al., 2014). For people in the community, consumer mHealth apps provide an opportunity to improve the management of their chronic condition (Schnall, Rojas, Travers, Brown III, & Bakken, 2014).

As with the advancement of technology, consumer mHealth apps have evolved with the patient-centred movement in healthcare. Patient-centred care focuses on the person as active in his or her care and central to the decision-making process (Ekman et al., 2011). While evidence-based care will always apply standardised care models, patient-centred care has been shown to further contribute to improved health outcomes and patient satisfaction (Ekman et al., 2011). This model fosters a greater sense of control over and confidence in their health which can be leveraged in consumer mHealth app use to become more active participants in their care (McNiel & McArthur, 2015). Users can experience an increased capacity to carry out a task (Moumtzoglou, 2016) for example, to access and track their health information (McNiel & McArthur, 2015). However, as with the variation of mHealth apps available to consumers, so does the quality (McNiel & McArthur, 2015). Particular concerns regarding the evidence of consumer apps include accuracy, efficacy and security (IMS Institute for Healthcare Informatics, 2015). Whilst apps are not routinely prescribed by healthcare professionals, there are more resources available for clinicians to be empowered to evaluate and recommend apps for their patients, such as the Health-related Mobile App Evaluation Criteria proposed by nurse researchers Ferguson and Jackson (2017). Recently, an Australian qualitative study investigating the perceptions of the current and perceived roles of general practitioners regarding consumer apps was published (Nguyen, Frensham, Baysari, Carland, & Day, 2019). The study found that general practitioners would be more comfortable recommending an app that was developed by credible source and evidence-based, and believed that mobile apps were the way of the future for healthcare, but were not yet integrated into their workflow (Nguyen et al., 2019).

Mobile health is a rapidly evolving domain with a developing body of knowledge. Published evidence regarding the impact of mHealth on patients with chronic conditions and to self-management has developed during the course of this research. In some instances, this literature has been incorporated into the publications in this thesis. However in summary, interpretation of the emerging literature has not been as positive as anticipated and important examples from the literature highlight this point. In a recently published metareview of 53 systematic reviews comprising 232 unique randomised controlled trials of telehealth interventions to support self-management of six chronic conditions (one of which was heart failure), the authors found inconsistent results (Hanlon et al., 2017). Although these reviews included telemonitoring and telephone interventions, the evidence regarding the impact of consumers apps in heart failure remains equally substandard. For example, an integrative review of 18 studies pertaining to commercially available apps which aim to support heart failure self-management found low-quality designs and small sample sizes, and combined with the variable outcomes measured, precluded the performance of a systematic review or meta-analysis (Athilingam & Jenkins, 2018). Accounting for the bias of this integrative review, the authors report that heart failure-related outcomes varied across the studies but demonstrated a trend towards making an impact (Athilingam & Jenkins, 2018). These two examples demonstrate the need to design and evaluate consumer mHealth apps in chronic conditions with rigour and further demonstrates the contribution of the research conducted for this thesis.

2.2 Preface to Publication 1

Publication 1 presents a focused scoping literature review on development processes of consumer mHealth apps for chronic condition self-management. A greater understanding was required in order to plan for the app development required for Phases I-IV. Specifically, an examination of the literature was needed to see if it was possible for a clinician to lead the development. Literature analysis included a greater understanding of the development teams, their roles, expertise and contribution. Secondly, the development processes including tools and techniques enlisted in each development stage as well as how the literature (guidelines, care pathways) were incorporated was needed. More holistically, the review evaluated the quantity and quality of academic literature reporting mHealth development processes accessible by healthcare professionals embarking on mHealth design projects like the one reported in this thesis. Consequently, the literature search included the health and medical databases.

The scoping literature review enabled a search of mHealth interventions aimed to support the self-management of chronic conditions. Classification of chronic conditions for the search conducted was as per the World Health Organisation (World Health Organization, 2014, p. 9). Four subgroups of chronic conditions have been highlighted as being the most common causes of mortality from non-communicable diseases (NCD) worldwide, totalling 82% of NCD deaths (World Health Organization, 2014). As per the report, the leading causes of NCD deaths in 2012 were (World Health Organization, 2014):

1. Cardiovascular diseases, representing 17.5 million or 46.2% of NCD deaths;
2. Cancers, representing 8.2 million or 21.7% of NCD deaths;
3. Respiratory diseases, representing 4.0 million or 10.7% of NCD deaths; and
4. Diabetes, representing 1.5 million or 4% of NCD deaths.

Therefore, for this scoping review, the following disease classifications were included: cardiovascular diseases (including stroke and heart attack); cancers; chronic respiratory diseases (including chronic obstructive pulmonary disease and asthma); and diabetes. Clear, transparent disclosure of the methods undertaken for the search was required for scientific and methodological rigour (Georgiou, 2016). Detail of the search process is provided in the methods section of the publication.

The citation for the publication, which is published ahead of print, is:

Woods, L., Duff, J., Cummings, E., & Walker, K. (2019, April 26). Evaluating the Development Processes of Consumer mHealth Interventions for Chronic Condition Self-management: A Scoping Review. *CIN: Computers, Informatics, Nursing,* vol. published ahead of print, issue p. doi:10.1097/cin.0000000000000528 The publication is available at CIN through https://journals.lww.com/cinjournal/Abstract/publishahead/Evaluating_the_Development_Processes_of_Consumer.99433.aspx

The final, revised author version is included in this thesis.

2.3 Publication 1: Evaluating the Development Processes of Consumer mHealth Interventions for Chronic Condition Self-management: A Scoping Review.

Abstract

Innovative, patient-centred mHealth interventions have the potential to help with the burden of chronic conditions. This review aims to describe the development of consumer mHealth interventions for chronic condition self-management. Using a scoping review methodology medical databases were searched and eligible reports were those published between 01/01/2010 and 31/12/2017 that provided information on consumer mHealth interventions for respiratory disease, cancer, diabetes and cardiovascular disease. Twenty-one reports were included, representing the development of 14 mHealth interventions. Most were collaboratively developed, using user-centred and participatory design processes. Pre-design work involved a thorough needs assessment and re-design processes were described as iterative, engaging with usability testing and design improvements. Tensions of competing priorities between patients and healthcare professionals were uncovered, with the intention to develop a useful product for the patient whilst ensuring clinical relevance. This review provides clear evidence that consumer mHealth interventions are developed inconsistently even when engaging with participatory or user-centred design principles, sometimes without direct involvement of patients themselves. Further, the incomplete description of the development processes presents challenges to furthering the knowledge base as healthcare professionals need timely access to quality information on mHealth products in order to recommend safe, effective consumer mHealth interventions.

Keywords

mHealth; consumer application; chronic disease; ambulatory care; review

Introduction

The management of chronic conditions has become a major focus for healthcare providers in our ageing population. Chronic disease self-management is often complex and challenging therefore innovative, patient-centred interventions are necessary to aid self-empowerment. Due to the relative affordability, portability and accessibility, eHealth and specifically mHealth, has immense potential to advance healthcare delivery and disease education.[1] The format of telemedicine has traditionally been bidirectional in nature where the sharing of health information assists with evaluation, diagnostics and treatment of patients.[1] Through automation and accessibility across various socio-demographic populations, mHealth interventions will advance to personal use far beyond the control of traditional healthcare services. This potential has seen an explosion of health

applications (apps) currently in the app store available to community-dwelling patients living with a chronic condition. Of the 318,000 plus health apps available to consumers world-wide, condition management apps are growing, now accounting for 40% of all apps.[2] Consumers have a plethora of choice for *disease-specific* management apps, accounting for 16% of health apps in 2017 with the top five therapy areas targeting chronic conditions.[2]

With the substantial growth in the body of evidence regarding the clinical impact of consumer mHealth interventions[2,3] but the varying quality available to consumers,[2] there is a necessary focus on rigour in the consumer mHealth market. Standards for mHealth development have progressed considerably and guidelines are now available; the World Health Organization's practical guide,[4] mHealth evidence reporting and assessment (mERA) checklist,[5] the Mobile Application Rating Scale (MARS),[6] guidelines for developers,[7] quality assessment using the AppScript Score,[2] and for chronic disease specifically in the Australian context.[8] An investigation regarding the particular processes essential for development of these interventions is necessary.

The objective of this review is to identify, summarise and report the medical literature on the development of consumer mHealth interventions for chronic condition self-management in the adult community-dwelling population reported in primary peer-reviewed studies.

Method

Design

The review follows the framework for scoping reviews as described by Arksey & O'Malley[9] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement noted by Moher et al.[10] The scoping review methodology allows inclusion of a broad range of study designs in a narrative account of the literature using a rigorous and transparent method which is described below.[9]

Identification of the research question

The research question followed an initial scan of the literature and discussions by the research team. Rationale for the question arose from the lack of easily accessible academic literature on development processes for mHealth interventions specifically for chronic condition self-management. This literature review seeks to answer the question: *How are consumer mHealth interventions for chronic condition self-management developed?*

Identification of relevant studies

CINAHL, Pubmed, PsychINFO and Embase were searched providing literature from databases accessible by healthcare clinicians. The combination of search terms used were; mHealth, mobile health, smartphone, smartphone application, mobile phone, self-management, self-monitor and self-care. Peer-reviewed primary studies published in English from 01/01/2010 to 31/12/2017 were deemed eligible. Reports needed to provide a description of the development of the mHealth intervention. For the purposes of this review, the intervention is defined as a single, specific self-contained software intervention on a portable mobile or tablet device used by community-dwelling individuals, which can be considered a self-management intervention or component of an intervention. It is considered a consumer intervention if health professional involvement is for emergency reasons (only) or the intervention is used as an adjunct to existing healthcare. The patient group was those diagnosed with a single, current and permanent main non-communicable disease (NCD) as defined by the World Health Organisation[11]; cardiovascular diseases; cancers; respiratory diseases (including asthma and chronic obstructive pulmonary disease), and diabetes.

Selection of relevant articles for the review

Reports from database searches where imported into the reference management system Endnote X7 and duplicates removed. Title and abstracts were screened for eligibility, then full text PDFs were analysed for content. The exclusion criteria included; regular health professional review or involvement in the intervention, diseases other than the named NCD, abstracts from conference and short papers which didn't describe development processes, among others (see PRISMA; Figure 1, Results section). Reports published since initial database search but before the reporting of the results, were added. The review pool included papers reporting development process and outcomes, with a subgroup reporting development processes only; these latter reports are examined within this scoping review.

Charting the data

Report data was extracted using a standardised form based on the McMasters University summary for qualitative[12] and quantitative studies[13] and managed using the database program Microsoft Excel.

Collating, summarising and reporting the results

To present a narrative account of the literature the authors applied an analytic framework[9] under three themes; pre-design, initial design and re-design of the interventions' development.

Results

A total of 2145 reports where identified from the databases; 305 from CINAHL, 667 from Pubmed, 152 from PsychINFO and 1021 from Embase. Duplicates (n=588) were discarded, resulting in 1557 reports which were screened. After review of titles and abstracts 1419 were excluded, leaving 138 full-text reports which were systematically assessed for eligibility. Ninety-five reports were excluded as they did not meet the inclusion criteria. This process yielded 43 reports for inclusion in the literature pool plus an additional five records found since the initial database search. Twenty-one reports described mHealth development. The PRISMA flow diagram in Figure 1 represents the identification, screening, eligibility and inclusion details.

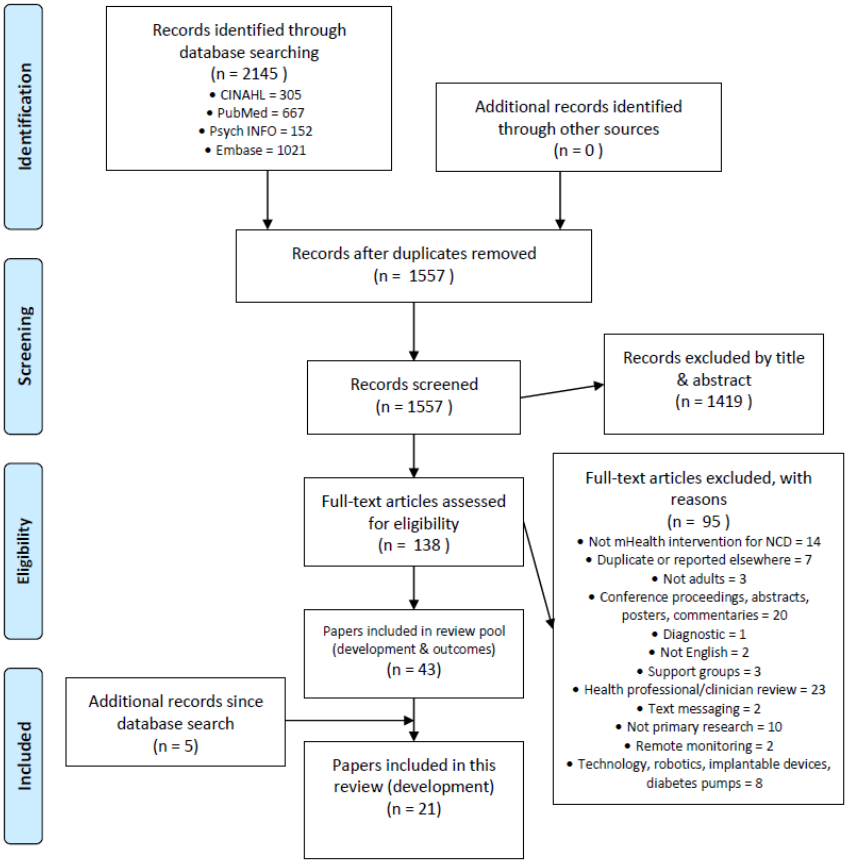

Figure 1 PRISMA flow diagram

Legend: NCD = Non-communicable disease

Twenty-one reports were included, representing the development of 14 mHealth interventions. Extracted report data was managed in Microsoft Excel and thereafter collated, summarised and reported as results. Table 1 identifies the mHealth interventions, reports associated with each intervention and study characteristics. Table 2 reports the development teams and development processes of the mHealth interventions described in the following results section.

Table 1 Evidence summary table; study characteristics

mHealth intervention		**Study characteristics**		
Name	**Condition**	**Location; publication year(s)**	**Framework for development**	**Evidence/source**
Few Touch Application[14-16]	Diabetes type 2	Norway; 2010, 2013, 2013	Design principle recommendations from the Norwegian Directorate of Health	ND
mHyptertension[a,17-20]	Hypertension	Sweden; 2014, 2014, 2014, 2015	The US Food and Drug Administration framework for the development of patient-reported outcome measures	ND
m.Carat[21]	Asthma and allergic rhinitis	Portugal; 2013	ND	ND
Bant ii[22]	Diabetes	Canada; 2016	Graham's Knowledge to Action Model blended with the Medical Research Council's framework for Complex Interventions	ND
Hypertension Management App[23,24]	Hypertension	Korea; 2015, 2016	The Web Roadmap methodology of information science	Clinical Practice Guidelines for hypertension management
HealthWeaver Mobile[25,26]	Cancer	USA; 2010, 2011	ND	Website version of the cancer website
Smartphone Application[27]	Asthma	Canada; 2013	ND	Canadian Asthma Consensus Guidelines;

				written asthma action plan
mAsthma[a,28]	Asthma	Taiwan; 2011	ND	Global Institute for Asthma guidelines
mCOPD[a,29]	COPD	Canada; 2015	ND	ND
Autonomy motivation & individual self-management for COPD patients (AMICA)[30]	COPD	Spain; 2015	ND	ND
Diabetes 101[31]	Diabetes type 2	USA; 2015	ND	2012 Standards of Medical Care in Diabetes
Vascular View[32]	Cardiovascular disease	Netherlands; 2017	The Intervention Mapping framework	ND
OASIS[33]	Cancer	USA; 2016	ND	ND
mHeartfailure[a,34]	Heart Failure	USA; 2016	Successive Approximation Model	Heart Failure Society of America guidelines; Mayer's Cognitive Theory of Multimedia Learning; Sweller's Cognitive Load Theory; Instructional Design Approach utilizing a Pedagogical Agent; problem-based learning

Legend [a] = mHealth intervention name pseudonym

ND = Not described

Table 2 Evidence summary table; development teams and procedures

mHealth intervention	**Development teams**			**Development procedures**		
Name	**Patients/ users**	**Health professionals**	**Experts**	**Pre-design phase**	**Initial design phase**	**Re-design phase**
Few Touch Application[14-16]	11-15 depending on the	ND	ND	Patient discussion; generation of design	Paper-based prototyping	Iterative; design testing; user-

	development phase			requirements; incorporation of user-centred design principles		experience data were incorporated in the iterations; Systems Usability Scale; tailor-made questionnaire; semi-structured interviews; focus groups; long-term engagement using qualitative analysis of longitudinal data
mHyptertension[a,17-20]	15, 21 and 50 patients involved in separate development phases	12 (physicians, nurses & pharmacists); then 4 healthcare professionals	7 researchers from interdisciplinary groups; 3 technical experts	Five focus groups; literature analysis	Group discussions; design meetings	Usability assessment; questions on the mobile device itself; semi-structured interviews; four rounds of 'cognitive interviews'
m.Carat[21]	8 users	ND	ND	Incorporated user-centred design principles	ND	Iterative; perform 10 standardised tasks and report difficulties
Bant ii[22]	(Validation with patients later)	ND	ND	Literature analysis	ND	ND

Hypertension Management App[23,24]	ND	ND	Expert group majoring in nursing and medical informatics and computer programmers	Engagement with experts	Extracted guideline content; hypertension management ontology development; tailored recommendations development	Mobile heuristics evaluation; usability assessment; scenario-based knowledge evaluation
HealthWeaver Mobile[25,26]	5 patients	ND	ND	ND	Content extracted and adapted from a website version	Iterative; feedback & prototype refinement; group discussion; white boarding; sketching; three small group meetings throughout a three-week period of prototype use; paper journal notes in-between meetings
Smartphone Application[27]	ND	ND	Clinical experts; experts from the Centre for Smart Community Innovation	Extracted guideline content; engagement with experts	Content from written asthma action plan	ND
mAsthma[a,28]	ND	ND	Taiwan Chest Disease Association and National Centre for High-Performance	Extracted guideline content; engagement with experts	ND	ND

			Computing personnel			
mCOPD[a,29]	Unknown number of patient participants	Unknown number	University Network's Centre for Global eHealth Innovation personnel; clinical leads from the University Health Network's Asthmas and Airway Centre	Requirement exercises with patients; patient interviews; engagement with experts	ND	Iterative; usability assessment
Autonomy motivation & individual self-management for COPD patients (AMICA)[30]	25 users	ND	Experts from pulmonology, usability, software engineering, graphical design, computational linguistics and designers	Requirement exercises with specialist physician; extracted guideline content; engagement with experts	Paper-based prototyping; sketching; steered by software engineers	Iterative; usability testing processes; feedback and prototype refinement; questionnaire; semi-structured interviews; 'talk out loud' processes
Diabetes 101[31]	ND	ND	Honours students; technical experts from the College of Arts and Sciences; faculty members from the College of Nursing	Extracted guideline content; engagement with experts	Addition of videos from previous work; experts provided technical expertise	ND
Vascular View[32]	6 patients	Medical, specialist	ND	Requirement exercises	Integrating the qualitative	Iterative; usability

		nursing & allied health professionals (psychologist, dietitian, physical therapist)		with end-users; literature analysis; selecting theory-based interventions	outcomes elicited from previous work; blue prints	assessment; open ended questions with comment section; interviews
OASIS[33]	15 patients	11 rural health clinic staff	ND	Requirement exercises; interviews; focus groups	ND	ND
mHeartfailure[a,34]	6 patients (alpha test); 10 patients (beta test)	Physicians, nurse practitioners, nurses; 4 nurses assessed credibility of information & design	ND	'The team' created heart failure educational modules based on guidelines; incorporated theories & models	Technical development of media	Iterative; alpha & beta testing; usability assessment; feedback and version refinement; self-confidence questionnaire; suggestions

Legend [a] = mHealth intervention name pseudonym

ND = Not described

Study Characteristics

Publication location was most commonly in the USA and Canada (7 interventions; 8 reports), followed by the European region (5 interventions; 10 reports) and Asia (2 interventions; 3 reports). The breakdown of NCD shows the majority of mHealth interventions were for the self-management of respiratory conditions (n=5), followed by cardiovascular diseases (n=4), diabetes (n=3) and cancer (n=2). Patient enablement of self-management was the most commonly reported impetus for mHealth development. The objective is to provide self-management support,[16,17,21-25,32] related to treatment adherence,[17,19] education,[34] skill development[29] and knowledge translation.[27,30] Behaviour

change modification was highlighted as a significant precluding development factor,[32] with physical activity or diet[16] and daily management challenges[23] a specific target.

Secondly, the healthcare environment was a common impetus for mHealth development. Development teams described the opportunity to address a gap,[32] to provide a novel, comprehensive, multi-component system[21,31] and better support information management.[25] Inconsistent access to health services,[22] especially at home,[28] in rural areas,[31,33] in real-time and in consideration of environmental factors specific to geographical areas[27] were context-related challenges potentially addressed through good mHealth design.

mHealth interventions were collaboratively developed. Design principles were articulated as being user-centred,[26,29,30] person-centred,[19] interdisciplinary[27,31] or participatory.[16,19,26,33] External frameworks used for mHealth development include; the US Food and Drug Administration framework for the development of patient-reported outcome measures[19]; design principle recommendations from the Norwegian Directorate of Health[15]; the Intervention Mapping framework[32]; the Successive Approximation Model[34]; the Web Roadmap methodology of information science[23,24]; and Graham's Knowledge to Action Model blended with the Medical Research Council's framework for Complex Interventions.[22]

Evidence-based information used for content development include the Global Institute for Asthma guidelines[28]; Canadian Asthma Consensus Guidelines[27]; Heart Failure Society of America guidelines[34]; Clinical Practice Guidelines for hypertension management,[23,24] the 2012 Standards of Medical Care in Diabetes[31]; and educational learning theories.[34] Two interventions relate to the direct adaption of content from other information sources; the website version of the cancer website[25] and a written asthma action plan.[27]

Development teams

Varied groups of individuals developed the mHealth interventions with patient and 'user' involvement common. The greatest number of patient participants reported in this review was for the development of *mHypertension*[a], consisting of 15, 21 and 50 patients depending on the development phase.[19] Most commonly, five to 15 patient participants with a diagnosis of the targeted condition were involved in the development.[15,17,26,33,34] Eight 'users' from different backgrounds were engaged to develop the *m.CARAT* application[21] and 25 users for the *Autonomy motivation & individual self-management for COPD patients (AMICA)* intervention representative of the target population in this case, senior users with limited computer skills.[30] One third (n=5) of the

mHealth interventions were not described as being developed with patient or user input.[22,23,27,28,31] None indicated development was initiated by patients themselves.

To a lesser extent, healthcare professionals were involved in development. Medical, nursing, allied health, rural health clinic, primary healthcare centre and medical clinic staff contributed to development processes.[19,21,33,34] The number of patient participant and healthcare professionals was not disclosed in the *mCOPD*[a] intervention abstract.[29]

Expert collaboration in the development of the included mHealth interventions was frequent. Experts were described as; Taiwan Chest Disease Association and National Centre for High-Performance Computing personnel[28]; experts from pulmonology, usability, software engineering, graphical design, computational linguistics and designers[30]; interdisciplinary researchers and technical personnel[19]; computer programmers and medical and nursing informaticians[24]; clinical experts in collaboration with expertise from the Centre for Smart Community Innovation[27]; and the University Network's Centre for Global eHealth Innovation personnel together with clinical leads from the University Health Network's Asthmas and Airway Centre.[29] A university collaboration for the development of *Diabetes 101* demonstrated teamwork between honours students together with technical experts from the College of Arts and Sciences and faculty members from the College of Nursing.[31] Details of researcher input is under-reported in the publications.

Development procedures

The progression of development is represented in this results section by three sequential phases, each incorporating various procedures. The first is the *pre-design* phase incorporating all the work before the formulation of the mHealth intervention, followed by the *initial design* phase comprising the procedures for developing the first version of the mHealth intervention, and lastly, the *re-design* phase relates to the activities for refinement and testing. The following results sections describe each phase including the processes conducted by development teams.

Pre-design

The reports provided a thorough explanation of participatory-based processes in the pre-design of mHealth interventions. It is an active process; much of the activities incorporate concurrent evaluation of the literature and design principles in addition to incorporating patient perspectives balanced with health professional perspectives. Pre-design work was predominantly expressed as a 'requirement analysis' or 'needs assessment' either for general users diagnosed with a chronic

condition or specific to the target users in a patient population. Requirement exercises were conducted with end-users,[32] patients,[29,33] clinical staff[33] or a specialist physician.[30] To gather these requirements, data collection methods comprised of patient interviews[29,33] and staff focus groups,[33] considering opinions regarding the role of technology in self-management.[33]

Requirement analyses are often specific to the context. For example, generation of design requirements was collaboratively established through patient discussion.[14] To balance patient and health professional perspectives, patients were asked the most valuable advice received during treatment and healthcare professionals detailed how they adapted such advice.[32] For the development of *mHypertension*[a], conducting five focus groups with patients and healthcare professionals allowed incorporation of the experience from their respective positions in the health service.[19]

Pre-design procedures involved assessment of the evidence-base as well as confirming context-sensitivity. Complementary activities included a literature analysis,[19] specifically regarding perceived problems and user needs with the opportunity to discuss with and prioritise together as a team.[32] The *Vascular View* research team selected theory-based interventions from the literature, translating techniques into practical applications and confirming whether they were appropriate for the target group by conducting a meeting with patients and healthcare professionals.[32] The *Bant ii* development group evaluated wearable devices using literature analysis, determining the appropriateness of a step counter as their patient group predominantly walk as a means of physical activity.[22] Researchers also analysed, extracted and adapted guideline content[23,24,27,28,34] to fit the context and perceived end-user requirements,[31] for example, incorporating specific visual content designs suitable for older people.[30] Educational learning theories were identified and analysed in the heart failure educational module formation for *mHeartfailure*[a].[34] Research teams incorporated user-centred design principles extracted from existing literature such that the intervention should be as simple and easy to use as possible,[15] user-friendly,[21] and took into consideration 'few touch' design principles[14] limiting time and effort by the end-user.

The roles of experts engaged in pre-design activities was incompletely described. Research teams who identified engagement with experts often did not describe details like frequency, duration and specifically who was involved.[23,27,28,31] When identified, engagement with experts related to broad content, features and usability recommendations.[29,30] A nurse faculty member described important components of diabetes self-management in the *Diabetes 101* intervention[31] and usability experts

and engineers defined the clinical specifications, context and user profile, and also incorporated interface design recommendations for elderly people in the *AMICA* intervention.[30]

Initial design

The initial design of mHealth interventions were seldom reported, but reported as incorporating information from preceding phases. Through integrating the qualitative outcomes elicited from previous work,[32] teams were able to define the required elements, confirm the system requirements and finalise the content.[30,32] Development methods for the initial design include paper-based prototyping,[14,30] sketching,[30] blue printing[32] and engaging in group discussions at design meetings.[19] Software engineers[30] or research teams[32] steered this process. Additionally, research teams adapted a website version,[26] added videos produced by previous honours students[31] and technically developed the media for the educational modules of their intervention.[34]

In this initial design phase, continued assessment of the literature was reported. The evidence-based knowledge and design principles were translated into mHealth intervention features as determined in the pre-design phase. Five hypertension-related Clinical Practice Guidelines[23] and the written asthma action plan[27] became the basis of the content realised through coding of the initial design, with adaption as deemed appropriate by development teams. For the *Hypertension Management App*, hypertension management ontology and tailored recommendations were developed, allowing for interface and functional requirements to be realised through coding.[24]

Experts were identified as being involved in the initial development of the mHealth intervention but infrequently detailed. In the university faculty-staff-student collaboration to develop *Diabetes 101*, experts provided technical expertise specifically working to ensure context-sensitivity so that end-users could relate to the content within the application.[31] For example, to allow relatability to the lifestyle of patients living in rural locations, experts strategically selected race, gender, ethnicity, language-use and dress of actors in the videos within the intervention.[31] Details about the specific roles of experts by other research teams were scant in this initial design phase.

Re-design

Publication information in the re-design phase all relate to activities using a participatory-based approach. Methods used by teams in the re-design of mHealth interventions were varied but were mainly described as an iterative design[14,21,26,29,30,32,34] engaging with usability testing processes.[24,29,30,34] Patient participants were involved in testing the designs[14] often in an iterative process incorporating feedback of new requirements by making a list of suggestions and user

requirements followed by prototype refinement.[26,30,34] Improvement suggestions were found to be mostly minor to incorporate into the next iteration.[15] Patient feedback showed, for example, that participants liked seeing the data whenever they accessed the system,[14] wanted to record more specific information relating to food details[14] and activity types,[15] and edit previously saved but incorrectly added data.[15] Usability issues were consistent across age groups[15] and aside from the times of technical difficulties, patients reported no additional burden on them to use the *Few Touch Application* for diabetes self-management.[14] Engaging with repeated iterations lessened usability issues[15]; specifically incorporating feedback from patient participants enabled the user interface to be as good as possible.[14] Furthermore, involving the *same* patient users throughout the process in an iterative fashion was demonstrated to elicit effective feedback.[16]

In addition to target users, healthcare professionals were consulted to assess the usability of four interventions.[19,29,32,34] Up to 50 patients and eight healthcare professionals were involved in the before-after study design evaluating the experiences of using the *mHypertension*[a] system.[19] Patients and clinicians did usability testing separately in the *mCOPD*[a] intervention.[29]

A wide range of data collection methods in the re-design phase were described. Questionnaires were predominantly used[16,30,34] including either tailor-made questionnaires,[15] open-ended questionnaires with comment sections,[32] the Systems Usability Scale,[14,16] or patients answering specific questions on the mobile device itself.[19] Other methods included conducting semi-structured interviews,[16,19,30] asking open-ended questions,[32] encouraging suggestions,[34] group discussion,[26] focus groups,[15] observation,[34] mobile heuristics evaluation,[24] scenario-based knowledge evaluation[24] and a 'talk out loud' process capturing thought processes whilst interacting with the application.[30(p6)] In the *m.Carat* intervention for asthma and allergic rhinitis self-management, 'users' were asked to perform 10 standardised tasks and report difficulties or problems.[21] Another method enlisted for content validity and usability was four rounds of 'cognitive interviews' conducted on a mobile phone where a set of items were presented and assessed for item comprehension, relevance and coverage.[19] For the research group developing the *Healthweaver Mobile* intervention, participants were asked to attend three small group meetings throughout a three-week period of prototype use, taking notes in a paper journal in-between meetings.[26] Tools enlisted during these meetings included sketching and the use of white-boards.[26] Location was only specified during the usability evaluation of the *AMICA* intervention: The evaluation was conducted in a lab-environment with senior users who had a limited relationship with technology and was conducted by usability experts and a psychologist/therapist.[30]

The length of usability testing of the intervention, whether described as a system or prototype ranged from one week[32] to three weeks.[26] The Norwegian research group[16] incorporated long-term data in the design iterations of the *Few Touch Application* for diabetes self-management. Aiming to detect design issues, they investigated long-term engagement using qualitative analysis of longitudinal data from 12 patients, incorporating feedback on usability from a 6-month intervention with new subset of patients not involved in the design phase.[15]

Experts from computer programming and medical and nursing informatics were involved in the re-design of *Hypertension Management App* for the purpose of identifying usability problems from a variety of diverse expert perspectives.[24] There is no link to the literature-base relating to re-design of these interventions.

Discussion

Principal results

Three main themes emerged from analysing development processes of consumer mHealth interventions for chronic condition self-management. These are user-centred design of mHealth in person-centred healthcare; the role of participatory design in mHealth intervention development; and tensions between healthcare provider and healthcare consumer. Each theme is discussed in the following section in the context of the broader literature and potential implications to development teams considering mHealth development in their specific healthcare environments.

User-centred mHealth design in person-centred healthcare

The impetus for innovations to address chronic condition self-management continues as healthcare providers aim to provide ongoing support to patients. Infrequent healthcare professional visits are inadequate to provide a complete solution to self-management as patients make *daily* decisions regarding food, lifestyle, exercise, medications and heath maintenance.[31] As mentioned, research teams often aimed to develop the mHealth intervention to address a gap in current healthcare delivery with the need for evidence-based accessible information[31] and education tools.[30] Accessibility to such tools was important, especially by rural health patients.[31,33] Articulating target user requirements as 'support needs',[18] aligns with patient-centredness, where the needs of the individual is directly incorporated into the design. For the *AMICA* intervention for COPD self-management, user characteristics were taken into consideration.[30] They developed a digital technology even knowing that rural patients may not have reliable internet access and therefore

adapted their design to require internet access for download only.[31] Consistent with the existing scoping literature review by Matthew-Maich et al,[35] recommendations from research findings and theoretical perspectives support the need for user-centred design approaches in mHealth development benefiting usability and feasibility.

Many of the procedures describe a patient-centric and context-sensitive model for development. Developers of the *Healthweaver Mobile* system,[25,26] for example report discovering an overall unmet need for tools for health information management, finding that such tools could decrease stress, allow more time and energy for patients to focus on their health. They found patient participants wanted the application to be customisable and also modifiable to their changing needs.[26] mHealth interventions were primarily seen to provide patients an option to be actively engaged in planning their care and in the decision-making process, central to person-centred healthcare.[19] Further, those who experienced a greater sense of control over their diabetes through using the *Few Touch Application* had a positive perception of the intervention which somewhat contributed to continued usage over the long term.[16]

Inconsistencies around true user-centred design were elicited through analysis of the reports within this review. The *Smartphone Application* study authors explicitly stated *no* users were engaged in the informal design process adapting the written asthma plan in a consultative process with an expert steering committee.[27] They then admitted 'future development will include a more robust design phase using [a] user-centred design philosophy'.[27(p305)] Additionally, patients and clinicians did usability testing separately in the *mCOPD* intervention, while the authors maintain that user-centred design principles were used.[29]

Results also indicate a strong foundation in the existing literature to incorporate into the design of novel mHealth interventions. The *perceived* user-experience is argued to add value to the design by examination of the existing literature. Although differing from previously reported articles which support the principle that patients should be actively involved in co-designing these interventions, the article by Goyal et al[22] justifies the important contribution the knowledge-base can provide in preparation of the initial design. During the development phase, researchers have the opportunity to collaborate with experts, extract guideline content *and* elicit findings from the literature but didn't demonstrate interacting with target end-users.[22,28] With the results of this literature review finding that most development teams use patient or users in the re-development phase for usability factors and validation of the end product, could justify their reasoning. Nevertheless, strategies to

balance the knowledge-base with the user requirements to develop a robust, relevant intervention, remains undefined. What follows is a discussion on the personnel involved in mHealth development.

Participatory design in mHealth intervention development

The evidence to enlist participatory design methodologies in mHealth development is strong. The growing consensus is that user participants should be actively involved in all phases of the design, development[30] and trial phase.[16] Notably, early patient engagement in the development process improves construct validity[30] as the design stems from the needs of the target user[19] specific to a condition and healthcare context. Continuing with participatory design methods, rapid prototyping and testing is seen as a beneficial process to analyse how technologies work in reality of everyday life[26] where a functional prototype can be assessed for usability.[16]

Evidence from this literature review supports the *iterative* development processes enlisted through participatory design particularly. Benefits in this process are demonstrated in design improvements and the addition of new requirements from the user which may not have been elicited from previous iterations.[30] Continuously assessing usability strengthens and then confirms a design that is valuable, functional and engaging.[29] This can be achieved through incorporating the output of each iteration as input into the next version of the prototype, until deemed satisfied by users.[30] These methods, however, can only be carried out using successful participatory engagement processes enlisted by development teams; this is an ongoing challenge in mHealth development. To maintain participant involvement, frequent visits aided motivation to continue participation in the Norwegian study on the long-term engagement with the *Few Touch Application.*[16] Regular visits and efficiently incorporating feedback also contributed to participants feeling satisfied with their contribution to research.[16] Another factor influencing development is participant selection. Tatara et al[15] recommends conducting usability testing on a new subset of patients who were not involved in the design phase, because this proved more beneficial in assessing perceived usefulness positively affecting the quality of the design iterations. No author divulged providing financial remuneration for participation.

Inconsistencies from the literature were apparent when extracting information about the stage and the extent to which patient users were involved. Development teams may be left asking the question; *Should patients be engaged throughout the development process, or before the initial design or in the re-design phase?* In the examples within this review, teams of researchers and experts conducted most of the labour in pre-design and initial design phases of mHealth development with selected patient engagement only. Regarding the *Vascular View* intervention for

cardiovascular disease self-management, the research group conducted the majority of the development while patients and healthcare professionals were engaged for validation and prioritisation of appropriate features and content.[32] Similarly, patients evaluated the *Hypertension Management App* after it was designed based on existing clinical practice guidelines and in consultation with experts.[23] The latter intervention focusses on two factors of hypertension management; lifestyle improvement and drug treatment.[23] An apparent paradox is evident if the intention is to support the self-management needs of patients themselves. If not consulted in the first instance, patient priorities for hypertension self-management may be inaccurately presumed or incorrect to the patient population. End-users' priorities for self-management require careful attention from the outset of development, and with a true patient-centred healthcare philosophy, how can we justify only engaging patients after development?

Strategic selection of participatory design teams may prove to be highly influential to the usability of the end product. Firstly, careful selection within the recruitment phase would impact the departure point of the mHealth intervention development. The benefit of participatory design is that the universal scientific knowledge can be balanced against the lay knowledge[20] and the prototype design can be tested at low risk from the perspective of potential end-users. Still, selection bias is a known limitation in participatory design where patients who are more likely to be adherent to guidelines, participate in research associated with adherence,[19] which may not be representative of the population of target users. Secondly, the intentions of participants involved may fundamentally vary from the research project aims. This is to be considered if we believe the intentions of the members of the development team influence the technology and development process itself, as suggested by Ranerup and Hallberg.[20] To engage with and prioritise the needs of the end-user with complete respect to the patient-centred model, development teams require ongoing management of the interactions between design team members. Significantly, management of the relationship between lay and evidence-based knowledge is necessary to appropriately facilitate the formation of a design that fits the multidimensional reality of everyday life of the end-user.[20] Importantly, clarity of research questions regarding for *whom* intervention development is for, is necessary from the project's inception.

Tension between healthcare provider and healthcare consumer

When designing patient-facing mHealth interventions, healthcare consumer and healthcare provider priorities may vary. Tension is a way to describe these competing perspectives. What follows is a discussion about patient priorities for self-management in the context of digital technologies for

condition self-management, the perspectives of healthcare professionals regarding self-management, and a summary of the balance between these two stakeholders.

Described thoroughly in the articles relating to the development of *mHyptertension*[a],[17] and as an example of the potential for tension which may affect mHealth design, patient and healthcare professional perspectives differed significantly. This study uncovered that overall, patients wanted more control in disease self-management. From the patient's perspective, becoming a 'participating and knowledgeable patient' was an important factor in hypertension management.[17] Patients prioritised the need to see relationships between symptoms, side-effects and understand the effect treatment had on their general health and family life.[17] Healthcare professionals however, were found to doubt patient self-management abilities. Healthcare professionals were uncertain their patients would become a 'participating and knowledgeable patient' and nurses specifically were hesitant that patients had the ability to understand and interpret blood pressure readings.[17]

The concepts of adherence and self-management seem to constitute this apparent tension. Self-management guidelines may not be appropriate and therefore not followed in the real world, which may be perceived as poor adherence.[20] For example lack of symptoms was uncovered to be a reason patients didn't take medicine.[17] Using ethnographic methodologies in their longitudinal study throughout the development of *mHypertension*[a], researchers 'detected the apparent paradox of introducing a self-management system for hypertensive patients and the intention to increase adherence'.[20(p 315)] If the healthcare professional's agenda is to increase self-care by, for example 'capitalising on teachable moments'[27,29] or through presenting clinical guidelines in a mHealth intervention, then the intervention may not be truly patient-centred. Reframing development goals may require a fundamental mindset shift from improving adherence to guidelines to fundamentally supporting the individual in the reality of everyday life living with a chronic condition.

Strategies to manage the balance between healthcare provider and healthcare consumer remains indeterminate. The reports within this review, however, uncovered support for a two-principle view on consumer mHealth intervention development. First, to develop a useful product for the end-user and secondly, to ensure its clinical relevance. Recommendations include the need for healthcare professionals to truly uncover the needs and circumstances of patients themselves and work towards mutually agreed upon treatment plans.[17] It is suggested when the design 'stems' from patients themselves, prioritising self-management needs are established from the outset, with ongoing healthcare professional input regarding their clinical relevance.[19] The combination of actual experiences and perceived problems of patients and healthcare professionals,[32] and the balance of

lay knowledge and scientific knowledge,[20] are two challenges development teams face to improve mHealth design. Effectively collaborating among stakeholders with differing interests is a consistent research finding in an existing literature review by Matthew-Maich et al.[35] Yet the mutual benefit for healthcare providers to support patient empowerment in disease self-management is the reduced need for active, real-time feedback by healthcare professionals, thus lowering financial expenditure, improving access and long-term sustainability.[22] In person-centred healthcare, healthcare professionals require the inevitable evolution to allow patients more equal control and move ahead of the traditional paternalistic and directive model of healthcare delivery.[36] With the recent expansion of digital technologies in the contemporary era and growing prevalence of chronic conditions we will see an inevitable increase in use of these technologies. Therefore, healthcare professionals need skills and knowledge to analyse, personalise and deliver quality research-based mHealth solutions as an adjunct to existing healthcare.

Recommendations for further research

This literature review reveals limited descriptive detail of design processes. Much of the existing literature relates to outcomes of mHealth interventions, content and features. The systematic process of development isn't thoroughly described, nor is it clear whom and in what specific capacity, persons are involved in development. Assuming the potential benefit of well-developed health technologies for improving the health of populations, researchers and developers would collectively benefit from sharing research outputs.

To manage the advancement in digital healthcare delivery, mHealth interventions must be evaluated through robust research, leveraging their potential in challenging, complex healthcare environments. Armed with more knowledge regarding quality user-centred design from the outset of the development process, contemporary healthcare teams could maximise the long-term health impact of digital technologies. Specifically, to manage potential tensions between healthcare provider and healthcare consumer, structured recommendations are required to deliver appropriately designed products with a balanced mix of patient and professional requirements. The challenge to development teams is to refine participatory design processes in the commitment of a true patient-centred healthcare culture. Importantly, refining methodological procedures to advance safe digital healthcare beyond the immediate control of healthcare personnel is recommended.

Limitations

Where possible, we have included all information available describing development processes in the results of this review, however the potential for omission of relevant reports is possible. The mHealth interventions involving multiple publications may have been disproportionately over-represented in the research findings. These include the two large research teams from Sweden and Norway and their respective mHealth interventions for hypertension and diabetes self-management.

One third of the mHealth applications were not described as being developed with patient or user input[22,23,27,28,31] in the pre-design or initial design phase, however may involve patient collaboration in later stages of development or evaluation. This may have biased the results to under-representing patient or user engagement.

Conclusion

While the literature on digital technologies in healthcare delivery is emerging, the number of peer-reviewed publications regarding the development of such technologies is small. The gap includes specific methods for the development of consumer mHealth interventions for the self-management of chronic conditions. This review contributes to the existing body of knowledge around mHealth design processes as reported in the medical literature, noting that due to the nature of the peer-review process it is likely these consumer interventions are of higher quality in comparison to the readily available applications on the commercial app stores. Most mHealth interventions included in this review were collaboratively developed, using user-centred and participatory design processes with patients, users, healthcare professionals and experts. Particularly, the re-design processes were described as iterative, engaging with usability testing and incorporating findings into design improvements. The main themes which emerged from the literature were the importance of user-centred design in person-centred healthcare of which was elicited from users themselves and the literature, and secondarily, the beneficial role of participatory design in mHealth development. Additionally, tensions of competing priorities between healthcare consumer and healthcare provider throughout mHealth development were uncovered, with the intention to develop of a useful product for the end-user whilst ensuring clinical relevance as deemed by healthcare professionals.

Consumer mHealth interventions that support patient empowerment and engagement in disease treatments have the potential to improve the patient experience and lessen utilisation of health services. mHealth interventions with their behaviour-change capabilities must be leveraged in the

context of population health, focussing on the need for responsible, sustainable and viable healthcare solutions in the contemporary era, to address the ageing population and burden of multi-morbid conditions. The goal in going forward, would be for mHealth designers to be alert to these potential tensions in the participatory design process, determining the true research questions to be answered, uncovering the genuine insights from patients (and healthcare professionals) and how to best manage these. With the erratic uptake of mHealth interventions in our current healthcare environment, robust research methods to advance mHealth quality is necessary. Importantly, collaborative work with patients to tailor mHealth interventions to ensure support needs are addressed remains a great challenge for development teams. Healthcare professionals need timely access to quality information on mHealth products in order to recommend safe, effective consumer mHealth interventions to complement existing healthcare services.

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2.4 Chapter 2 summation

Information revealed through exploring the literature on mHealth development processes informed the research methods. A greater understanding was gained about the teams who develop mHealth interventions and the ways in which teams conduct design and development processes. First, literature analysis determined that development processes require a structured, phased and iterative approach, especially important to define as the lead clinician researcher was new to the domain. This would require learning and borrowing techniques from outside of nursing, like design and innovation. Second, collaboration with, and across, various stakeholders were needed to plan for an intervention which would support patients with heart failure, family members who are frequently involved and clinicians who provide heart failure care and self-management support in the current healthcare environment.

Informed by the realisations uncovered in this chapter and in line with the research philosophy, a pragmatic and person-centred research approach was undertaken. A description of the research objectives and the research phases conducted including the methodological approach to the research is described in Chapter 3.

Chapter 3 : Research methods

This chapter includes a publication representing an overview of the methods, followed by a more in-depth description on the methodology and study procedures. The formation of four research objectives was informed by studying the literature in the domain of mHealth development. The data analysis phase of the scoping literature review was insightful as the study procedures were being drafted. Finally, the methodological approach and study procedures were established. To address each research objective, a research phase was conducted. Therefore, this thesis has four research phases.

Chapter 3 is divided into the following sections:

Section 3.1 introduces Publication 2, which summarises the methodological approach and the app development process;

Section 3.2 presents Publication 2 - *Design Thinking for mHealth Application Co-Design to Support Heart Failure Self-Management* which was published in Studies in Health Technology and Informatics in 2017;

Section 3.3 provides further explanation on the methodological approaches. In this sub-section, Design Science Research Cycles framework, the Design Thinking process and co-design principles are described;

Section 3.4 presents the study procedures of the four-phased research design. Study procedures involved various methods of data collection and analysis due to the phased development of the app and the many stakeholders involved. Only an overview of the study procedures is provided, as the procedures of each research phase are detailed within the publications contained in Chapters 4-7;

Section 3.5 explores the ethical considerations of conducting the research; and

Section 3.6 which provides a summation on Chapter 3.

3.1. Preface to Publication 2

Publication 2 presents an overview of the methodological approach to the research and the app development process. It reports the research plan and was written before study procedures commenced. The reader is introduced to Hevner's Design Science Research Cycles (Hevner, 2007) and how it was modified to the context of mHealth app development. The framework signifies the

importance of incorporating relevance and knowledge into the design of a new innovation. It was embedded into app development processes. The development process was modelled from the Design Thinking process which is a 5-stage innovation process defined by Stanford University (Hasso Plattner Institute of Design at Stanford University, 2017) which is outlined in the 'design process' section of the publication.

Studies in Health Technology and Informatics published this work in the series 'Context Sensitive Health Informatics: Redesigning Healthcare Work'. It was an accepted, peer-reviewed article and presented at the Context Sensitive Health Informatics Conference held at City University, Hong Kong in 2017. The article was published online with open access by IOS Press and distributed under the terms of the Creative Commons Attribution Non-Commercial License.

The citation is as follows:

> Reprinted from Studies in Health Technology and Informatics, vol. 241, Woods, L., Cummings, E., Duff, J., & Walker, K., Design Thinking for mHealth Application Co-Design to Support Heart Failure Self-Management, pp. 97-102, Copyright (2017), with permission from IOS Press. The publication is available at IOS Press through http://dx.doi.org/10.3233/978-1-61499-794-8-97

The Design Science Research Cycles framework was used and adapted with kind permission from the original author, Professor Hevner (see Appendix B). Further detail on the methodological approaches used in this research which were not published in Publication 2 is included in the subsequent sections in this chapter.

3.2 Publication 2: Design Thinking for mHealth Application Co-Design to Support Heart Failure Self-Management

See next page.

Context Sensitive Health Informatics: Redesigning Healthcare Work
C. Nøhr et al. (Eds.)

doi:10.3233/978-1-61499-794-8-97

Design Thinking for mHealth Application Co-Design to Support Heart Failure Self-Management

Leanna WOODS[a,b,1], Elizabeth CUMMINGS[a], Jed DUFF[c] and Kim WALKER[a,b]
[a] *School of Health Sciences, University of Tasmania, Australia*
[b] *St Vincent's Private Hospital Sydney, Australia*
[c] *School of Nursing and Midwifery, University of Newcastle, Australia*

Abstract. Heart failure is a prevalent, progressive chronic disease costing in excess of $1billion per year in Australia alone. Disease self-management has positive implications for the patient and decreases healthcare usage. However, adherence to recommended guidelines is challenging and existing literature reports sub-optimal adherence. mHealth applications in chronic disease education have the potential to facilitate patient enablement for disease self-management. To the best of our knowledge no heart failure self-management application is available for safe use by our patients. In this paper, we present the process established to co-design a mHealth application in support of heart-failure self-management. For this development, an interdisciplinary team systematically proceeds through the phases of Stanford University's Design Thinking process; empathise, define, ideate, prototype and test with a user-centred philosophy. Using this clinician-led heart failure app research as a case study, we describe a sequence of procedures to engage with local patients, carers, software developers, eHealth experts and clinical colleagues to foster rigorously developed and locally relevant patient- facing mHealth solutions. Importantly, patients are engaged in each stage with ethnographic interviews, a series of workshops and multiple re-design iterations.

Keywords. Co-design, Design Thinking, mHealth, application, heart failure, self-management

Introduction

Heart failure is a highly prevalent chronic condition and major burden to the Australian healthcare system [1, 2] costing in excess of one billion dollars a year [3]. In Australia, up to half of all patients initially hospitalised with heart failure will be re-hospitalised within 3-6 months [3]. While heart failure often shows an adverse trajectory towards morbidity and mortality, out-patient self-management is an important practice to improve symptoms and quality of life. Self-management involves the person monitoring their own health supported by their clinicians, with the aim to limit the worsening of symptoms by daily symptom monitoring and addressing deterioration promptly and effectively [4]. Recommended self-care regimes, such as those set by the Australian Heart Foundation [4, 5] are perceivably complex and often challenging to maintain [6].

[1] Corresponding Author: Leanna Woods: Email: leannaj@utas.edu.au

Our primary aim is to co-design a mHealth application to improve heart failure self-management in the out-patient population at St Vincent's Private Hospital Sydney. A secondary aim is to evaluate the user-experience of the application by patients themselves. The overall objective of this research is to improve patient symptom self-management and assist with specific evidenced-based guideline requirements improving clinical outcomes, enhancing patient self-efficacy and subsequent satisfaction with their disease management. This paper describes the proposed development methodology for the mHealth application.

1. Methodology

A structured framework, the Design Science Research Cycles outlined by Hevner [7] will be followed to ensure a high quality product. Comprising three cycles, the framework applies design science to IT systems. We have modified the framework to fit with our healthcare context as demonstrated in Figure 1;

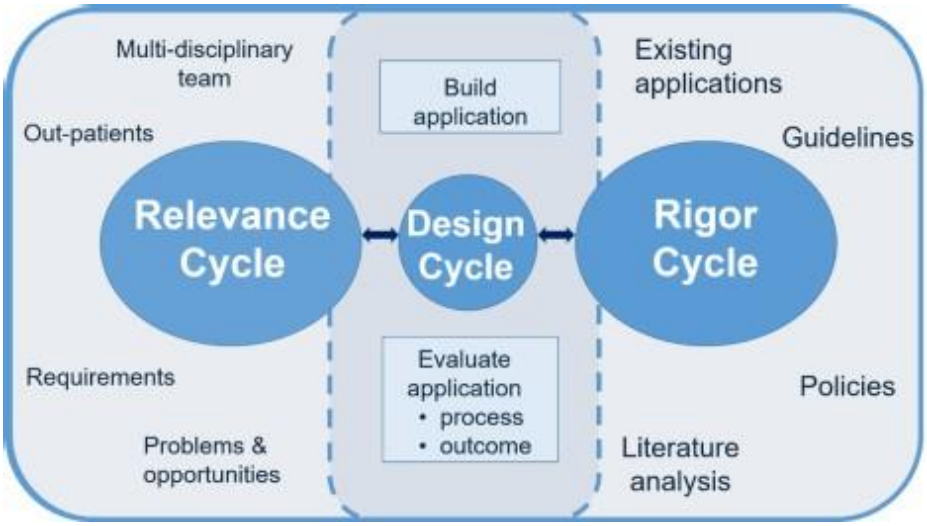

Figure 1. Modified Design Science Research Cycles [7]. (Used and adapted with kind permission from the original author)

1.1. Relevance Cycle

The relevance cycle relates to the context; specifically, the requirements of out-patients with heart failure, their carers, and the perspectives of interdisciplinary team members who regularly care for this patient population. This empathetic process uncovers what is important in the context of everyday life [8] both as a healthcare consumer and healthcare provider to ensure app content is user-centred and clinically relevant. The relevance cycle not only encompasses the current perspectives ('problems'), but also captures the possibilities of what the future of heart failure care may look like ('opportunities') from a variety of opposing perspectives.

1.2. Rigor Cycle

The rigor cycle relates to knowledge. It focuses on acknowledging the contribution of the existing knowledge base regarding mHealth application design, health literacy, behaviour change theory and the local and national heart failure policies and guidelines. Conducting ongoing literature analyses through academic literature, grey literature and local (internal) publications is the basis of these rigor exercises, ensuring the app content is consistent with the current healthcare delivery of heart failure services to our patient population.

1.3. Design Cycle

Application development is informed by both the relevance and rigor cycles in an iterative, cyclical fashion. Continuous evaluation of the design maintains relevance to end-users and consistency with the knowledge base.

2. Design process

A series of rigor and relevance exercises initially and continually inform the design of the mHealth application using Stanford University's Design Thinking Process [9]. The Design Thinking Process was used with the aim to produce a well-designed product meeting the requirements of the end-user from the outset, supporting a patient-centred healthcare philosophy. It is a systematic innovation process that prioritises deep empathy for end-user needs and challenges to fully understand a problem in order to then develop a comprehensive, effective and technically viable solution [8].

Design Thinking prioritises:

- Developing empathy through comprehensive understanding of a problem,
- Radical collaboration incorporating opposing mindsets, and
- Rapid prototyping engaging users in the iterations [8]

The Design Thinking Process is a five phase innovation process which may be fluid or linear depending on the progression of the design; empathise with the end-user, define the problem, ideate a solution, prototype by building a solution and test with the end-user [9].

The project is a hospital-university collaboration conducted on site at St Vincent's Private Hospital Sydney inclusive of the following team members;

Table 1. Co-design team from the hospital/university campus

Patients	Carers	Clinicians	App developer	Research team
Adults with heart failure	Provide supportive care for an adult with heart failure	Nurse Practitioners Cardiologist Cardiac Clinical Nurse Consultant Dietitian Physiotherapist Pharmacist	University affiliate	Doctoral candidate Supervision team

2.1.1. Empathise

Ethnographic interviews, conducted with self-selecting patients and their carers recruited from the hospital, allow for a deep understanding of their daily life living with, and self-managing, heart failure. It uncovers insights and elicits the requirements of the end-user. Previous work conducted by this research team in the same healthcare context investigated fluid restriction self-management specifically, discovering patients found self-management complex, tiring and challenging [10]. These previous study participants demonstrated limited skills to self-manage symptoms in their homes, many misunderstood the treatment rationale and were often confused about the benefits of adherence [10]. Posters containing personas and a patient journey map will be developed to visually represent the findings of this phase; the unique needs and insights of end-users which can be leveraged into the application design.

2.1.2. Define

Based on these needs and insights from phase 1, the healthcare problem needs clarity. Specifically, the design team define a list of opportunities regarding maintenance and improvements in the self-management of heart failure in the out-patient setting relative to our patients needs and based on the local guidelines and policies. For example, the design criteria may include facilitating knowledge [11], improving cognition [12, 13], and developing problem solving skills [14] in this patient population.

2.1.3. Ideate

A two-hour collaborative design workshop with all members of the co-design team is to be conducted on the hospital campus for the purpose of idea generation. Using a collection of creative thinking activities (for example, Idea Matrix, Rose Thorn Bud, Visual Vote), a multitude of perceivably effective strategies are generated based on team members' experiences and exposures from a range of perspectives. Field notes, matrix content and photographed images of the generated ideas on posters will be the basis of the data collected.

2.1.4. Prototype

The second workshop uses convergent thinking approaches to select the best ideas in order to make a visual prototype. Using an Impact/Effort Matrix when considering possible solutions, the design team actively draw a storyboard of how an end-user would interact with the solution, always referring to the user's needs and knowledge base as a cross-reference. The team *proceed* with low effort/high impact solutions in the first instance, *consider* low impact/high effort solutions, *investigate* high effort/high impact solutions and *disregard* high effort/low impact solutions.

Storyboard content (and sequence) is finalised during the workshop and then transferred to wireframe format to allow for prototype refinement based on feedback from end-users. Importantly, this stage engages patients themselves facilitating multiple feedback/ re-design iterations to ensure an appropriately tailored product.

Once the design team achieves consensus regarding the features and functions of the wireframes, a software prototype is promptly synthesised by the application developer. Based on a collective summary of individual feedback from the design team

members and importantly patients themselves, two further iteration cycles of the mHealth application result in the completion of this phase.

2.1.5. Test

Finally, the prototype is tested with a new subset of 12 patients using a validated tool to assess usability. Participants interact with the mHealth application prototype for 14 days in the home setting and thereafter report their experience of using the application. The Mobile Application Rating Scale (MARS) [15], together with app analytics provided by the IT partner and qualitative interviews conducted by the student researcher will be used to evaluate the application from the perspective of the end-user.

3. Discussion

Innovative, patient-centred interventions which improve heart failure self-management benefit patients and healthcare providers alike. In the Australian state where our hospital is located, the most likely location of discharge after a hospital admission for heart failure is home (73%) [16]. But nearly half of these patients are re-hospitalised with heart failure within 3 to 6 months [3], with suboptimal self-care a contributing factor. This is true even when over half of these patients are referred to a multidisciplinary heart failure service (59%) [16]. Therefore, the importance of supporting our patients in self-management in the home setting is overwhelmingly necessary. Encouraging and facilitating patient engagement and empowerment could decrease hospitalisations by teaching self-care skills specific to the healthcare context, patient socio-demographic population and the existing evidence-based guidelines already in place. The resultant app is for out-patients to use in addition to regular heart failure care provided by our hospital's interdisciplinary team.

Design Thinking is one possible process to truly uncover the needs of the end-user in context and develop a unique product necessary to complement existing complex, chronic contemporary healthcare services. In a recursive, dynamic manner design team members involved in each design process activity re-familiarise and discuss relevance and rigor content from the Design Science Research Cycles, expediting a fit-for-purpose solution. Indirectly, the application could benefit healthcare providers by decreasing the frequency and duration of health professional interactions. With an increasing emphasis on co-design with end-users, it is necessary to engage with patients, health care professionals and technologies to foster sustainable, viable healthcare solutions in a contemporary, ageing healthcare environment.

4. Conclusion

Interdisciplinary healthcare research in mHealth leads to quality systems benefiting the end-user. The potential for improvements in sustainable and efficient healthcare are endless with mHealth systems but only if they are tailored to the end-user and supported by rigorous research. We must evaluate systematic design processes like Stanford University's Design Thinking Process used by this research team, to provide a

robust evidence-base for our speciality in our pursuit of context-sensitive health technology design for the advancement of patient-centred care.

Acknowledgments

This research is supported by a St Vincent's Clinic Foundation Grant and the University of Tasmania's Elite Research Scholarship funded by The District Nurses. No conflicts of interest.

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3.3 Methodological approaches

Chapter 1 (section 1.3) described the research philosophy. In a practice discipline like nursing and where the intent is to make positive change for the purpose of healthcare improvement, a pragmatic and person-centred approach was necessarily appropriate. This influenced the approach to which the research objectives would be addressed and how the study procedures were designed. The chosen methodological approaches were:

1. **Design Science Research Cycles**, which is a framework signifying the importance of designing a solution which has relevance to the environment and was consistent with the knowledge base;
2. **Design Thinking process**, which provided structure to the innovation process including specific tools and techniques from outside the health research domain; and
3. **Co-design principles**, which provided ways to engage with, and between, stakeholders.

In the following sections of Chapter 3, each methodological approach is described and justified for inclusion in this research.

3.3.1 Design Science Research Cycles

A detailed overview of the Design Science Research Cycles was provided in Publication 2 (section 3.2). This framework was used to develop a product that is both developed with rigour and relevant to the stakeholders involved. The approach recognises that design is a pragmatic science and the synergy between relevance and rigour is necessary in making a contribution that has practical utility *and* is developed from a solid knowledge-base (Hevner, 2007).

During the conceptualisation and planning of the research the modified Design Science Research Cycle (presented in figure 1, Publication 2) was intended to be used. However, during the design and development of the app it became evident that the proposed framework required modification and application to the context. This resulted in the final modified version of the Design Science Research Cycles which is described in Figure 1. The final version accurately reflects the operationalisation of the framework in the context of in-hospital mHealth development, retrospective to the development process undertaken in the current research.

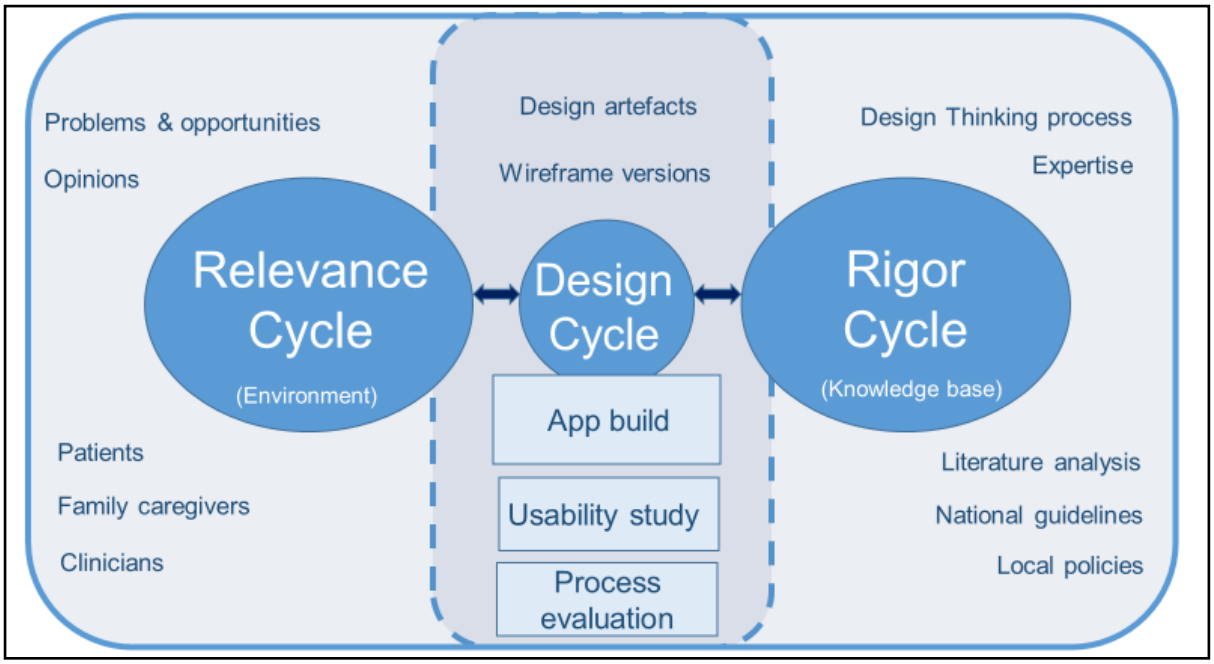


FIGURE 1. FINAL MODIFIED VERSION OF THE DESIGN SCIENCE RESEARCH CYCLES REPRESENTATIVE OF THE OPERATIONALISED DEVELOPMENT PROCESS: MID-2018

The final modified framework differed in several ways to the proposed framework, as described below:

- In the relevance cycle, stakeholders were correctly labelled. Rather than non-specific labels ('out-patients' and 'multidisciplinary team'), stakeholders were named as patients, family caregivers and clinicians for clarity and consistency with the language used in publications.
- In the design cycle, specific design elements were listed: design artefacts; and wireframe versions. Through learning about design, it became evident that the design cycle includes research outcomes from each phase rather than just the app build itself. Hence, the final version of the framework included design artefacts (as research outputs from Phase I) and wireframe versions (research outputs from Phase II). Section 3.4 describes these study processes in more detail.
- In the rigor cycle, existing applications were removed because this was not a focus in the development of the app. It was initially anticipated other heart failure support apps would be reviewed by the co-design team, however app store searches did not yield suitable, potentially comparable apps of quality. In regard to national guidelines and local policies, the co-design participants reviewed these resources during, rather than before co-design activities took place. An ongoing iterative review of the guidelines and policies was conducted as needed, and based on which app section the team was developing. It was

important that this literature was not simply replicated in an app interface, so we chose not to look at the literature initially, only accessing it as required. Study processes of how, and when, the literature was incorporated is described in detail in Publication 6 (section 5.4). Methods are also acknowledged in the rigor cycle, so the Design Thinking process was added to the final version.

Other mHealth app development teams used the Design Science Research Cycle framework during the time of this research. The framework was applied to the user-centred design and system development of a mHealth technology for HIV prevention (Schnall et al., 2016). The authors conclude by stating that the use of the framework is a 'potentially useful approach for the design of a mobile app that incorporates end-users' design preferences' (Schnall et al., 2016, p. 243). The framework was also used in the design and build of a mHealth system for heart failure where the system was to be used by both patients and nurses (Alnosayan, Chatterjee, Alluhaidan, Lee, & Houston Feenstra, 2017).

3.3.2 Design Thinking process

Design Thinking is 'a systematic innovation process that prioritises deep empathy for end-user desires, needs and challenges to fully understand a problem in hope for developing more comprehensive and effective solutions' (Roberts et al., 2016, p. 12). The way Design Thinking is used in practice can differ. This research adopted Stanford University's interpretation of Design Thinking. Figure 2 represents the Design Thinking process as a five-phased process of innovation (Hasso Plattner Institute of Design at Stanford University, 2017).

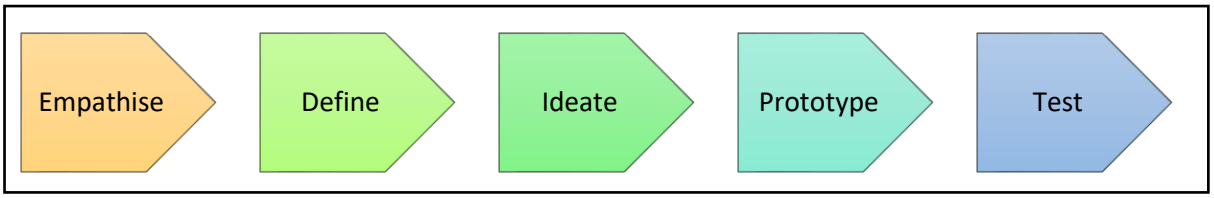


FIGURE 2. DESIGN THINKING PROCESS

Design Thinking is a common topic in the business community (Roberts et al., 2016). Perhaps the most significant application of the Design Thinking methodology is the contribution by Apple and Steve Jobs. The Apple software company has been pivotal to our understanding of the behaviours of humans interacting with computers. From the company's beginnings in 1976, Steve Jobs and

colleagues exemplified the Design Thinking approach in information systems. With the birth of Macintosh OS X circa 1990 Cordell Ratzlaff, who was a senior Apple architect at the time said:

> We did the design first. We focussed on what we thought people would need and want, and how they would interact with their computer. We made sure we got that right, and then we went and figured out how to achieve it technically (Thomke & Feinberg, 2009, p. 2).

This quote demonstrates the clear focus on the *individual* as opposed to the traditional customer; this person-focused philosophy is more familiar today than in previous decades (Thomke & Feinberg, 2009). Steve Jobs' vision was to seek a 'beautiful elegant solution that works' (Thomke & Feinberg, 2009, p. 10) stating 'simplicity is the ultimate sophistication' (Thomke & Feinberg, 2009, p. 3). From the beginning, and consistent with the Design Thinking philosophy, Apple implemented an iterative customer involvement strategy in product design and development in successful efforts to help customers 'love' their piece of technology (Thomke & Feinberg, 2009). Apple products' design is completely focused around the user's experience of working with it and the most likely cause of the company's continued success (Thomke & Feinberg, 2009). Now, Design Thinking has evolved from use in technology companies to entrepreneurs, start-ups, small business and even healthcare.

Regardless of the potential to embed new ways to view existing challenges, the uptake of Design Thinking to the health sector has been sluggish (Roberts et al., 2016). This highlights the need to describe and evaluate the application of Design Thinking in the sector. Developing capacity for Design Thinking in healthcare could see benefits like embedding change and innovation safely in healthcare systems to address the complex, multidimensional challenges that exist in health (Roberts et al., 2016). Perhaps the biggest shift in adopting such innovative processes stems from healthcare's recent transition to the patient-centred movement where healthcare consumers are more active, empowered and at the centre of their care, than ever before.

During the time of this research, a research group in New York has overlayed Design Thinking and other contemporary innovation approaches from industry, to propose a pragmatic process model of user-centred digital health development (Chokshi & Mann, 2018). They published their proposed model in 2018. They argue the strength of their approach is one which is multidisciplinary, creative, flexible, efficient, effective and importantly, guides development from within a health service (Chokshi & Mann, 2018). Also in 2018, Hendricks, Conrad, Douglas, and Mutsvangwa (2018) proposed a new stakeholder participation assessment framework for Design Thinking projects, signalling the emerging need to evaluate the participation of various stakeholders.

The Design Thinking process complements the pragmatic approach to the research described in section 1.3 Research philosophy. Design Thinking was embedded in the study procedures in two ways. First, on the phased approach to the design and development of the app and second, the methods and techniques borrowed. These will be explained in section 3.4 Study procedures.

3.3.3 Co-design principles

The principles of co-design were embedded in the research for a variety of reasons. First, design approaches need to account for the inherent power differences that exist in healthcare settings (Burford, Park, Dawda, & Burns, 2015). Second, collaborative, interdisciplinary approaches to the development of mHealth is imperative to enhance feasibility, acceptability and usability of the innovation (Matthew-Maich et al., 2016). So it is not simply the chosen methods that facilitate effective action research like co-design, but the attitudes of researchers which affect how the research is conducted (Schneider & Whitehead, 2013). Consequently, co-design principles facilitated stakeholder interactions and fit with how Design Thinking is conducted.

Co-design is a design-led process incorporating creative and participative principles and tools to actively involve a diverse group of stakeholders to explore, develop and test solutions to shared challenges (Blomkamp, 2018a). Co-design is practiced in many different formats however, the research philosophy explained in Chapter 1 aligns well with the co-design principles described by Blomkamp (2018b). Blomkamp's principles had some beneficial attributes which complemented the research context. First, the principles were developed locally. The co-design principles were inspired by the principles identified by the New South Wales Council of Social Service (NSW Council of Social Service, 2017) and industry experience conducting co-design in practice in the Australian context. Second, the principles allowed flexibility. Blomkamp (2018b) explains that these co-design principles draw on the philosophical underpinnings of participatory design without demanding a prescriptive or rigid approach which may be unachievable in practice. As a current co-design practitioner with academic roots, Blomkamp suggests those embarking on co-design wishing to improve outcomes in their respective fields and engage a diverse group of people in a meaningful way, focus on the mindsets or principles to realise the transformative potential that it offers (Blomkamp, 2018b).

The descriptions of the principles of co-design are as follows (Blomkamp, 2018b):

a) **Outcomes-focused**: This principle is about achieving change and having a positive impact, not simply about the outputs themselves;

b) **Inclusive**: Various people with different types of knowledge are included in the process whether it be lived experience, professional or specialist expertise;
c) **Participative**: The people involved are active participations providing meaningful input throughout the process, not simply tokenistic consultation;
d) **Respectful**: The input of people involved is valued and considered equal, as all those involved are considered experts; and
e) **Adaptive**: Co-design is experimental with the aim to innovate therefore it involves feedback loops, trial and error, learning and iteration.

Co-design is an emerging area of practice. Greater access to resources to conduct co-design in practice have emerged during the time of this research. An approach which has gained prominence in the body of literature is that of Experience-Based Co-Design (EBCD). For example, a toolkit for Australia was developed by Prestantia Health for the Australian Healthcare and Hospitals Association and Consumers Health Forum of Australia in 2018 (Dawda & Knight, 2018). This resource built on other EBCD work conducted in the United Kingdom, including reflections on projects that used this process by Donetto, Pierri, Tsianakas, and Robert (2015). More freely available resources for co-design in the healthcare sector provide access for non-designers, like clinicians, to take charge of design typically conducted by designers. However, despite the increasing interest in co-design and co-production in recent years, there is a lack of rigorous evaluation of how it is conducted in acute-care settings as uncovered by the rapid evidence synthesis conducted in 2017 by Clarke, Jones, Harris, and Robert (2017).

In the following sections, the study procedures of Phases I to IV are summarised. It is to be noted that the publications in Chapters 4-7 (representing Phases I-IV) contain a detailed method section, so the following presents a summary or detail not provided in the publications.

3.4 Study procedures

Four phases of research were undertaken to systematically address four research objectives. The research phases were:

I. Stakeholder perspectives prior to app design and development;
II. Collaborative design and iterative development;
III. Usability test with patients; and
IV. Process evaluation.

Study procedures were informed by Design Science Research Cycles, Design Thinking and co-design principles. The Design Thinking process allowed the segmentation of the research phases reported in this thesis. Figure 3 represents the relationship between the Design Thinking process and the research phases.

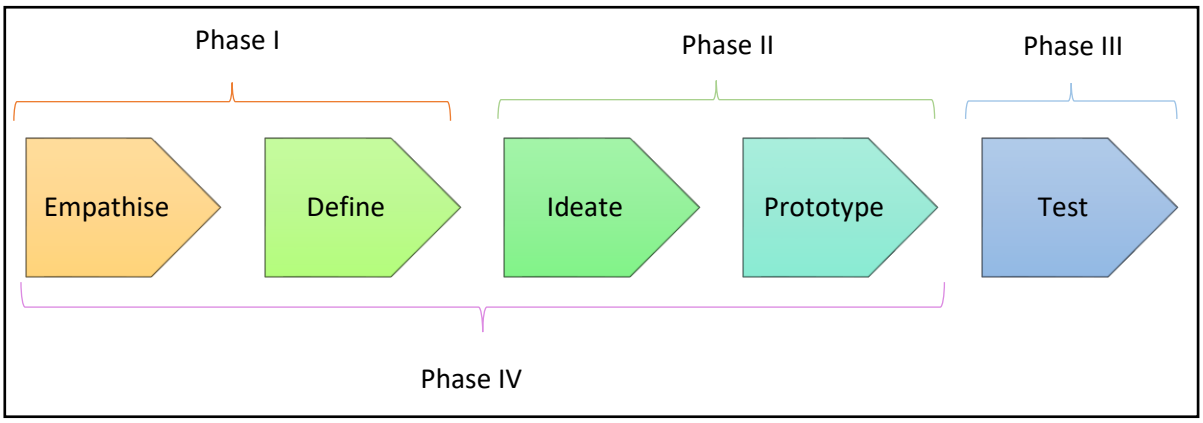


FIGURE 3. RELATIONSHIP BETWEEN THE DESIGN THINKING STAGES AND THE RESEARCH PHASES

The four research phases encompassed a variety of participants, data collection and data analysis processes. Methods of data collection and analysis from the Design Thinking paradigm, often referred to as 'tools and techniques', enhanced traditional health and nursing research methods. These tools and techniques were strategically selected for each research phase, depending on the requirements of the phase regarding the procedures and participants involved. Figure 4 presents the Design Thinking tools and techniques, and traditional health research methods, used in the four research phases. Detail on the methods for data collection is provided in this section, in addition to respective publications.

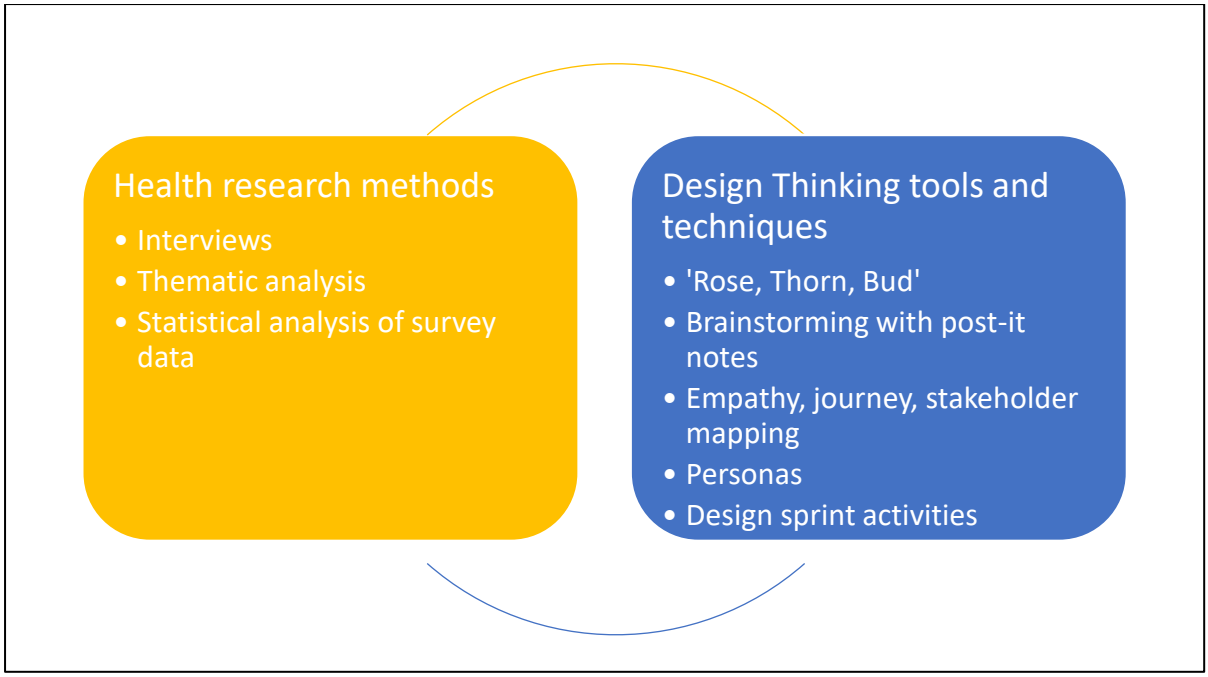


FIGURE 4. HEALTH RESEARCH METHODS AND DESIGN THINKING TOOLS AND TECHNIQUES

A summary of the phases undertaken is provided in Table 2.

TABLE 2. SUMMARY OF THE STUDY PROCEDURES FOR EACH RESEARCH PHASE

Phase	Participants	Procedures	Data collection	Data analysis
I. Stakeholder perspectives prior to app design and development	7 patients, 4 family caregivers	Interviews	Empathy map	Content analysis
	7 clinicians	Interviews	'Rose, Thorn, Bud' technique and brainstorming session	Initial code by clinicians, affinity diagram
II. Collaborative design and iterative development	7 clinicians, 3 patients, 1 family caregiver	Co-design workshops and prototype feedback sessions	Workshop activities, wireframe feedback template	Collaborative as the design progressed
III. Usability test with patients	New subset of 8 patients	14-days using the app at home and mixed methods evaluation	Interview questions, Mobile Application Rating Scale	Quantitative: statistical analysis in Excel Qualitative: Braun & Clarke's thematic analysis
IV. Process evaluation	7 clinicians, 3 patients, 1 family caregiver	Interviews	'Rose, Thorn, Bud' technique and brainstorming session	Initial code by participants, affinity diagram

The table explains the similarities and differences between participants, procedures and methods for data collection and data analysis. Detail of each research phase is explained in the sections hereafter.

3.4.1 Phase I: Stakeholder perspectives prior to app design and development

The objective in Phase I was to explore perspectives on heart failure self-management from a variety of stakeholders prior to the design and development of the app. The two stakeholder groups were:

i) Patients and family caregivers; and
ii) Clinicians.

Study procedures differed for the two stakeholder groups. The reason for this was the strategic selection of data collection and data analysis methods to answer the stakeholder-specific aims of Phase I. Below, the study procedures of the patient and family caregiver stakeholder group are summarised, then the study procedures for the clinician stakeholder group are presented.

Patient and family caregiver stakeholder group

The aim of Phase I for the patient and family stakeholder group, was to (1) understand the experience of people with heart failure and their caregivers in the local patient population, and (2) visually represent these experiences. Patients with heart failure and family caregivers were recruited and interviewed using an empathy map for data collection. Interview content was analysed and visually represented in a variety of visual formats.

Participants

Seven patients (4 female, 3 male) and four family caregivers (3 male, 1 female) self-selected to participate. Recruitment posters were displayed in common areas of St Vincent's Private Hospital Sydney (Appendix C). St Vincent's Clinic was added as a recruitment site because participant recruitment was slow, possibly associated with recruiting in an acute care setting where patients are at their most vulnerable (Willis, Robinson, Wood-Baker, Turner, & Walters, 2011). Local clinicians who worked in the two cardiac in-patient units were informed of the research through departmental education sessions conducted by the lead clinician researcher.

The inclusion criteria for adult patients with heart failure was the following:

- Diagnosis of heart failure;

- English-speaking;
- Lived at home;
- Cognitively and emotionally capable to participate; and
- Not in the palliative stage of heart failure or highly dependent on medical care.

Family caregivers participated through the same recruitment process, to provide their perspective on heart failure self-management from the perspective of the informal caregiver. Eligibility was assessed to ensure the person with heart failure they care for fitted the inclusion criteria. Self-selecting family caregivers participated regardless of the participation of their loved one with heart failure. The participant information sheet and consent forms for patients and family caregivers, is located in Appendix D.

Data collection

Semi-structured, face-to-face interviews were conducted between May and August 2017. An empathic approach to the interviews was used to uncover participant experience data. In the context of user-centred design, Wright and McCarthy (2008) define an empathic approach as beginning with a deep understanding of people's life contexts involving a meaningful dialogue between the researcher and participant. A modified empathy map (Dam & Siang, 2018) was used during the interview for the collection of data which is represented in figure 1, Publication 3 (section 4.2). Indicative interview questions are listed in Appendix E.

Data analysis

The participant experience data was used to form a needs and insights summary uncovered from empathy map content, along with a journey map and stakeholder map. These processes are detailed in Publication 3 (section 4.2). Although these research outputs from Phase I are referred to as visual representations of experience data, they are termed design artefacts from Chapter 5 onwards, as described in the terminology section (section 1.6). Design artefacts are material objects that can be viewed by others, used to challenge perceptions and inspire new ideas (Lupton, 2018).

Clinician stakeholder group

The aim of Phase I for the clinician stakeholder group was to conduct a needs analysis with multidisciplinary team members who care for people with heart failure, prior to the design of the mHealth application. Specific goals were to gather information regarding self-management support features of the application and the clinical requirements in planning for the application's successful implementation. Clinicians were interviewed on site the hospital campus. Using the 'Rose, Thorn,

Bud' technique from Design Thinking and a brainstorming session with post-it notes, perspectives on heart failure self-management were gathered from the perspective of the healthcare provider. A modified affinity diagram was used to analyse the data.

Participants

Multidisciplinary clinicians were purposefully recruited based on their regular and direct involvement in the care of adults with heart failure on the St Vincent's Hospital Sydney Campus. A targeted call for participation in the research occurred via email or face-to-face communication. A research charter was attached to the call for participation which outlined the study aims, procedures and other particulars (Appendix F). The following seven clinicians expressed their interest to participate in the research and were onboarded to Phase I. Table 3 lists their position and the location(s) of employment across the hospital campus.

TABLE 3. ROLE, DEPARTMENTAL AND ORGANISATIONAL AFFILIATION OF CLINICIAN PARTICIPANTS IN PHASE I

Role	**St Vincent's Public Hospital Sydney**	**St Vincent's Private Hospital Sydney**	**St Vincent's Clinic**
Cardiologist	Heart failure specialist	Heart failure specialist	Heart failure specialist
Nurse practitioner	Heart Failure Service		
Nurse practitioner	Heart Failure Service		
Clinical nurse consultant	Cardiac Rehabilitation		
Physiotherapist		Physiotherapy	
Clinical dietitian	Dietetics		
Pharmacist		Pharmacy	

Data collection

Interviews were conducted on the hospital campus over a two-week period in August 2017. One clinician responded via email exchange. Two broad questions were asked. The questions and the method of data collection are summarised below and discussed in more detail in Publication 4 (section 4.4).

1. *How do we support heart failure self-management at our health service?* The 'Rose, Thorn, Bud' technique from Design Thinking (Luma Institute, 2012) was used as a method for assessing: what is done well; what is not done well; and what could be done better.
2. *The application needs to be clinically relevant to our health service: How can we do that?* Clinicians' thoughts and ideas were documented directly onto post-it notes. Probing questions facilitated explanatory responses.

Data analysis

Initial coding of data by clinicians, by writing directly on specifically-coloured post-it notes, facilitated commencement of data analysis during the interview. Thereafter, data analysis was done visually. A modified affinity diagram (Weprin, 2016) was used to group and label similar responses resulting in an overview of these findings. Explanation of this process is provided in the methods section of Publication 4 (section 4.4).

3.4.2 Phase II: Collaborative design and iterative development

The objective for Phase II was to collaboratively design and develop a mHealth app with patients, family caregivers and clinicians. The research format for the collaborative design and iterative development represents a design process. Output from one stage of the design process served as input to the next stage as explained in the following sections and represented in Figure 5. The main stages were the conceptual design and iterative development stages, each containing processes therein. Conceptual design activities occurred in two multi-stakeholder co-design workshops. Iterative development activities involved the creation of wireframes which were iteratively refined in feedback sessions conducted with individuals in the co-design team. Two cycles of feedback sessions were required before the software version was built by the app development partner.

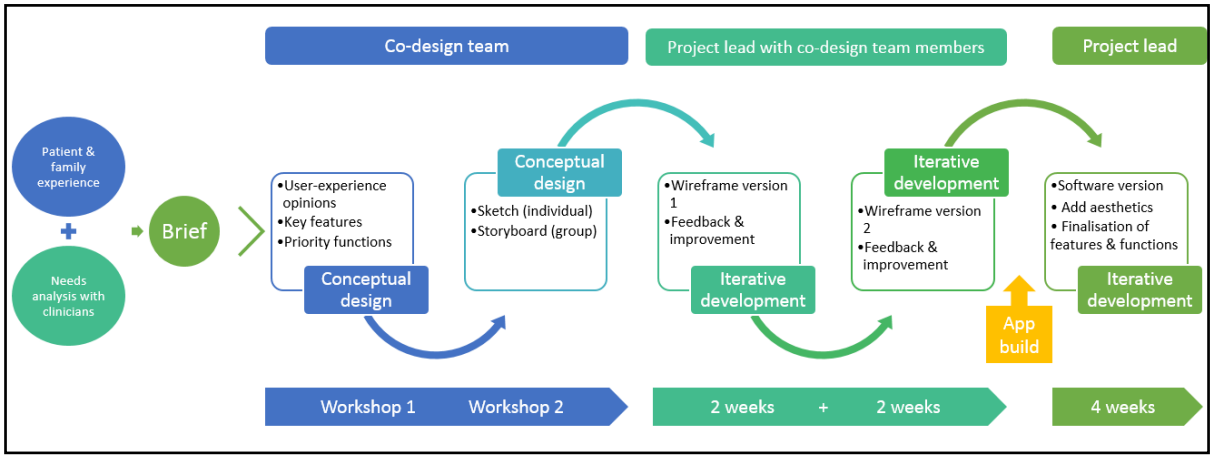


FIGURE 5. DESIGN AND DEVELOPMENT PROCESSES, PERSONNEL AND TIMELINE (DUPLICATED FROM PUBLICATION 6, SECTION 5.4)

In the following sections the participants of Phase II are identified, then a detailed description of the conceptual design and iterative development stages are provided.

Participants

All participants and clinicians from Phase I were invited to participate in the conceptual design activities conducted in two 2-hour co-design workshops. Six clinicians and one patient chose to attend. Participants, regardless of their participation in the workshops, were asked to participate in the iterative development of the app by attending prototype feedback sessions. All seven clinicians, plus three patients and one family caregiver chose to participate as represented in Figure 6.

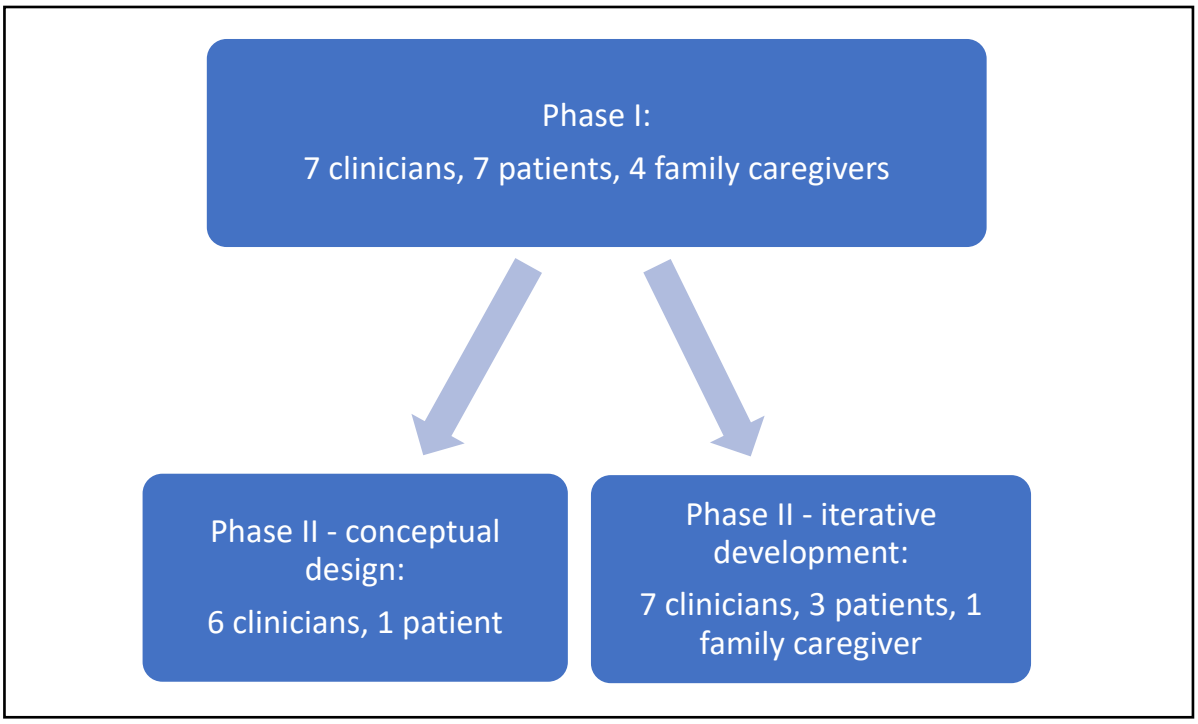


FIGURE 6. VOLUNTARY PARTICIPATION OF VARIOUS STAKEHOLDERS IN THE CONCEPTUAL DESIGN AND ITERATIVE DEVELOPMENT ACTIVITIES IN PHASE II

Conceptual design: Data collection and analysis

Conceptual design activities occurred in two 2-hour multi-stakeholder co-design workshops conducted on the hospital campus. Workshops comprise a set of activities on selected themes and group conversations on issues (Kanstrup & Bertelsen, 2011). Workshop activities were primarily based on design sprint activities (Knapp et al., 2016) with the purpose to make visions for possible futures (Kanstrup & Bertelsen, 2011) and were facilitated by the lead clinician researcher. Supportive leadership of participants aimed to achieve the activity goals and foster creativity through an approach to 'guide the design without dictating it' as suggested by Skeels & Pratt (2008). This involved the creation of a supportive environment where participants could represent their own needs, constraints, goals and priorities (Skeels & Pratt, 2008). In the workshop the lead clinician

researcher did not focus on Design Thinking as a methodology or structured innovation process as it was deemed unnecessary information for participants. Rather, the concepts of Design Thinking (such as divergent and convergent thinking, collective decision making and voting) were operationalised when activities were undertaken. These details are provided hereafter.

Workshop one

The first workshop was conducted on the 19th September 2017 as the highest number of volunteer participants could attend that date. Participants were welcomed to the meeting room, provided refreshments and an opportunity to meet each other. The planned design workshop activity 'Impact/effort matrix' identified in Publication 2 (section 3.2) was omitted from the workshop as other methods for prioritising important features and functions to be included in the conceptual design of the app, were included instead. The activities conducted in the workshop are described in the next paragraphs.

The first activity was 'Lightning Demos', based on the design sprint activity (Knapp et al., 2016). Workshop participants were divided into two groups and asked to evaluate their personal smartphone apps they considered useful, enjoyable and easy to use. Group discussion was an opportunity to share, discuss and refine key ideas. The activity was timed and materials such as post-it notes, markers and butchers' paper were provided. Figure 7 represents the instructions provided to participants displayed as a PowerPoint presentation slide in the meeting room alongside a digital timer.

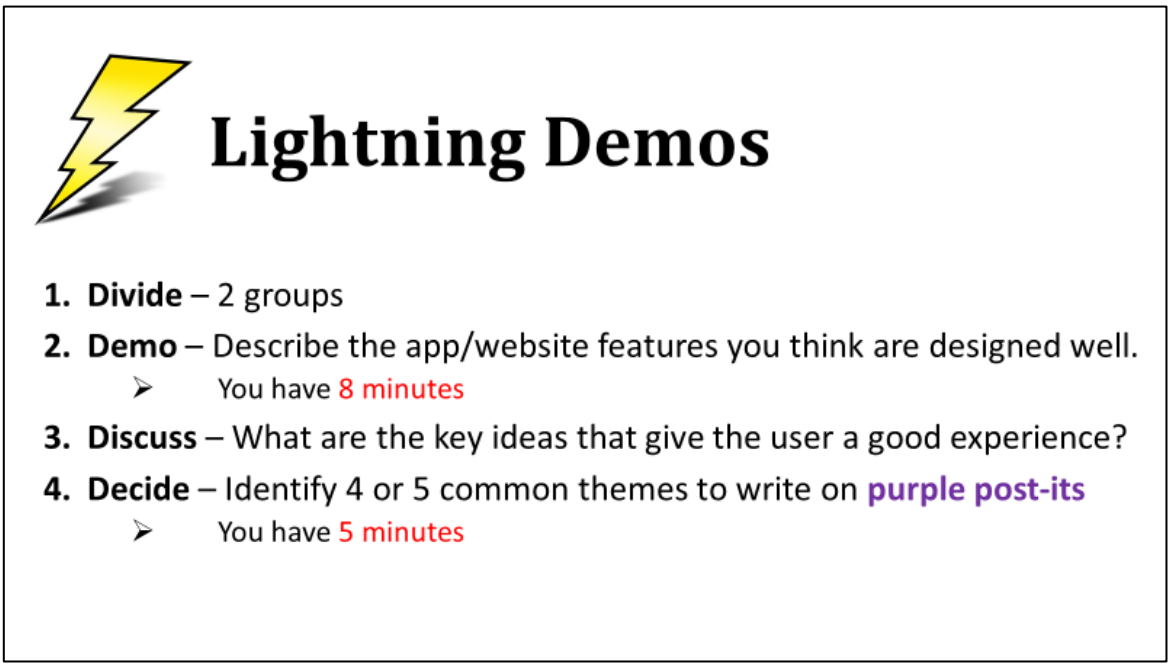


FIGURE 7. LIGHTNING DEMOS WORKSHOP ACTIVITY - INSTRUCTIONS FOR PARTICIPANTS

The second activity in workshop 1 was a 'Creative Matrix'. The activity was adapted from a Design Thinking technique where '*How might we…*' questions are asked to spur creative, divergent thinking about existing problems or challenges. The activity commenced after participants were introduced to four patient personas which were developed from the analysis of Phase I findings. Personas are fictitious characters based on research data, that represent potential target users (Nielsen, 2011). A thorough explanation of the development and use of personas is presented in Publication 5 (section 5.2). As per the instructions to participants represented in Figure 8, the Creative Matrix activity involved a brainstorming session with post-it notes containing potential solutions to health challenges associated with each patient persona.

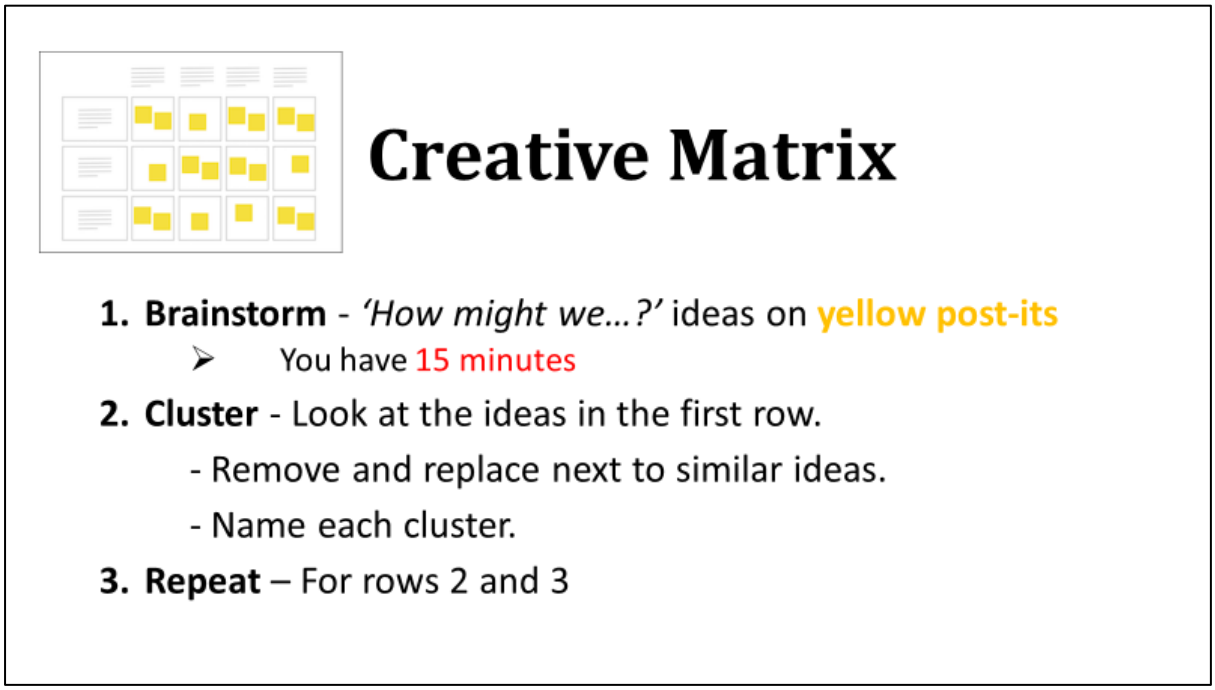


FIGURE 8. CREATIVE MATRIX WORKSHOP ACTIVITY - INSTRUCTIONS FOR PARTICIPANTS

Data analysis by workshop participants facilitated a summary of solutions representing the possible design. Participants did this through clustering similar solutions and labelling each cluster to represent its content.

Before the completion of workshop one, participants were asked to list their overall thoughts on ideas generated from the workshop activities. During this 'Greatest Hits' activity, participants looked around the room, selected the ideas they liked and left their list in the meeting room after the completion of the workshop. Instructions for participants to conduct the 'Greatest Hits' activity is provided in Figure 9.

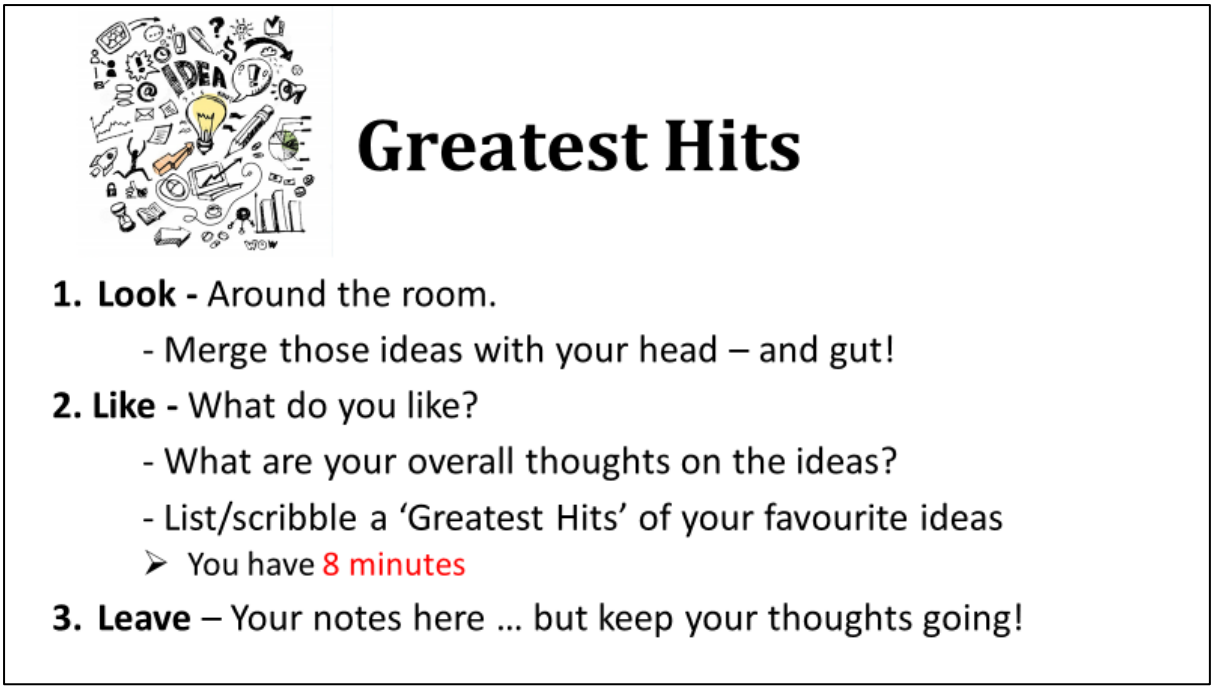


FIGURE 9. GREATEST HITS WORKSHOP ACTIVITY - INSTRUCTIONS FOR PARTICIPANTS

Data analysis by the lead clinician researcher was conducted after the completion of the first workshop. Field notes, photographs and individual summaries from the 'Greatest Hits' activity were further summarised resulting in three groups of concepts. These groups of concepts were represented in infographic format within posters:

1. User-experience opinions and key features (see Appendix G); and
2. Priority functions (see Appendix H).

A summary of the results of this data analysis process is located in Table 1, Publication 6 (section 5.4). A sample of photos taken during workshop 1 is located in Appendix I.

Workshop two

A second multi-stakeholder workshop was conducted two weeks later on 26th September 2017. The aim of the second workshop was to progress the initial design concepts to a refined design from which wireframes could be built. The same participants attended the second workshop and it was conducted in the same meeting room on the hospital campus.

At the start of the second workshop co-design team members reviewed and discussed the poster content, adding three more design concepts. Group discussion provided re-introduction to the concepts of heart failure self-management and designing an intervention to address this healthcare

challenge. By allowing additional ideas to be added to the posters demonstrated the meaningful engagement of workshop participants in shaping the app's design, rather than tokenistic participation (Blomkamp, 2018b).

In the 'Solution Sketch' activity (Knapp et al., 2016), participants worked individually to draw a sketch outlining how a patient would interact with the proposed app. Each participant was asked to select one health problem from one persona and step through the sequence of screens required for the user to address this health problem. A piece of A4 paper was divided into thirds. The first third represented the initial frame, then the subsequent thirds represented the frames which followed. Instructions for participants were displayed in the workshop as per Figure 10, along with an electronic timer.

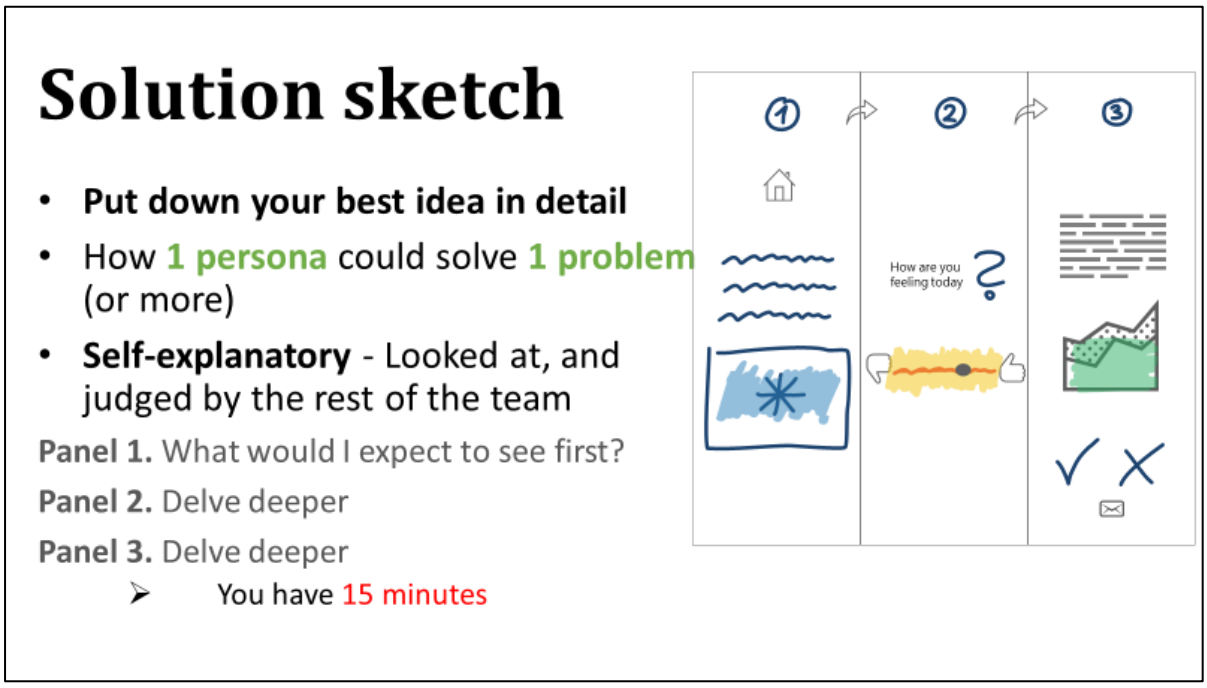


FIGURE 10. SOLUTION SKETCH WORKSHOP ACTIVITY - INSTRUCTIONS FOR PARTICIPANTS

Participants were asked to share their sketch with the team, vote on the parts they liked and collaboratively decide on standout ideas by listing them on post-it notes as 'main features'. Participants were encouraged to refer back to the design brief in making judgement calls about included features.

The final workshop activity was the creation of a 'Storyboard' (Knapp et al., 2016) of the app. Here, the main features and functions of the app were collaboratively created on a whiteboard which had

been divided into multiple blank squares before the workshop. Through facilitated group discussion and a volunteer scribe, participants selected 'main feature' post-it notes and added detail. The instructions for participants are presented in Figure 11.

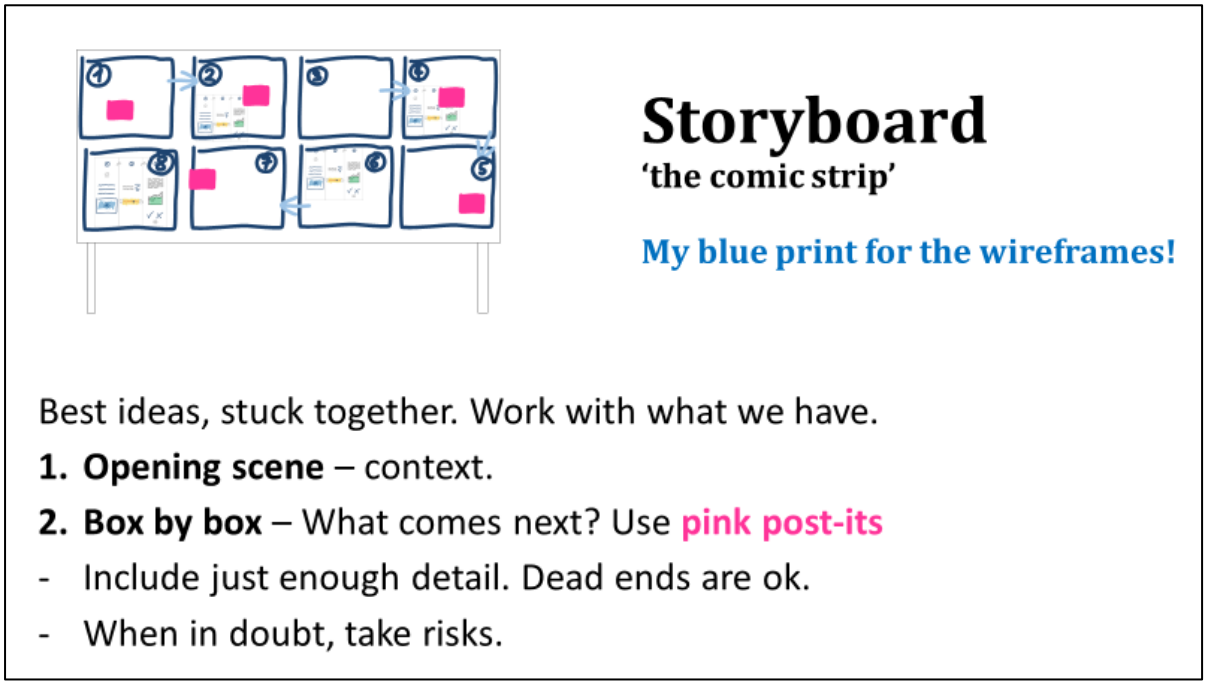


FIGURE 11. STORYBOARD WORKSHOP ACTIVITY - INSTRUCTIONS FOR PARTICIPANTS

Content within each box was considered input to the iterative development activities described hereafter. See Appendix J for the storyboard of the app and Appendix K for sample photos from workshop 2.

Iterative development: Data collection and analysis

The iterative development stage commenced with the creation of wireframes, a visual, interactive representation of app screens on a laptop computer. Wireframes were produced by the lead clinician researcher using a Microsoft PowerPoint software add on called PowerMockup (Wolfsoft, Germany, ©2018). Generic app templates, icons, directional features and clickable hyperlinks are some of the software features provided in this software. PowerMockup was navigated by the lead clinician researcher who had no previous experience in app or wireframe design. An example screenshot from the PowerMockup software is provided in Appendix L. The advantage of developing wireframes as a digital prototype is creating a realistic use situation where the user can gain a feeling of functionality behind the user interface (Kanstrup & Bertelsen, 2011). Wireframes were updated in

feedback sessions conducted individually with clinicians, patients and family caregivers (either in person or via email). See Figure 2 in Publication 6 (section 5.4) for the wireframe feedback template used in these sessions. The iterative development of the wireframe versions was repeated until there was consensus that the features and functions of the application were accurately represented. The various wireframe versions are located in the Appendix as per the following list:

1. Initial wireframes, developed from the storyboard activity conducted in the second workshop: Appendix M;
2. Wireframes after the first iteration, representing feedback and improvements made with one complete cycle with participants: Appendix N; and
3. Wireframes after the second iteration, representing the final version which was sent to the software partner: Appendix O.

Finally, the app was built by the software partner in January 2018. The lead clinician researcher worked closely with the software partner in the build phase using the online collaboration tool Trello.com (Trello®, Atlassian, ©2018). Sample screenshots of the Trello online workspace during the software build are located in Appendix P. Importantly, the lead clinician researcher worked to ensure the desired features and functions from the final wireframe version were included in the build. The colour palette, logo graphic and icon design were confirmed with only minimal input from participants. A patient participant named the app 'Care4myHeart'. The debugging and finalisation processes were completed by the end of April 2018 after nine software builds. During this time the lead clinician researcher conducted ongoing tests as a web app, on an iPhone handset via the Testflight app and an Android handset via an APK file. The software partner provided the following details regarding the software specifications of the app build and testing details:

> The Care4MyHeart app was made using the Apache Cordova tool for cross-platform mobile development, with code written in HTML, JavaScript, and CSS (using the Framework7 codebase as a start). Software used included Sublime Text 3 (text editor), XCode (for iOS version), and Android Studio. Development consisted of a single codebase for both Android and iOS (with minor differences for each platform). Development of the website (for distribution of the app) was also done using Sublime Text 3, again in HTML, JavaScript, and CSS. The site (and app downloads) are hosted by the NeCTAR research cloud of which the University of Tasmania is a partner.
>
> Testing was conducted on real Android and iOS devices as well as simulators. The application is a closed-beta only, meaning that the application cannot access the internet and data is stored only locally on the phone. The server is used only to store the app download for the Android version, and for displaying installation instructions. The Android version of the application will continue to be hosted on

NeCTAR for the duration of the beta phase. The iOS version of the application is hosted by Apple, and will continue to be hosted for the duration of the beta phase (this involves uploading a new build (even with no changes) every 80 days).

The software build represented the end of Phase II. The user interface of the *Care4myHeart* app is presented in Publication 7 (section 6.2).

3.4.3 Phase III: Usability test with patients

The objective for Phase III was to understand the patient experience using the app for heart failure self-management in the home setting. Specific research questions were:

1. What were the patients' experiences of using the *Care4myHeart* app; and
2. What is the perceived impact of the app on heart failure self-management?

Phase III involved a 14-day usability study of the mHealth app conducted with a new sample of self-selecting patients. A mixed method evaluation was used to uncover qualitative and quantitative information about patient impressions of the app in relation to heart failure self-management. The Mobile Application Rating Scale (MARS) (Stoyanov et al., 2015) was used to evaluate app quality and usability. This was accompanied by interviews to uncover qualitative information. A mixed-methods evaluation including thematic and statistical analysis was conducted. App use was self-reported by participants themselves as no ethical approval was granted to collect usage data, which is in contrast to the anticipated research plan reflected in Publication 2 (section 3.2) reporting that 'app analytics' would be used. The procedures undertaken in Phase III are provided below and detailed in Publication 8 (section 6.4).

Participants

Patients with heart failure self-selected to participate in the usability study. Recruitment posters were displayed in common areas of St Vincent's Private Hospital Sydney (see Appendix Q). The inclusion criteria for Phase III were the same for Phase I in addition to owning a smartphone device which would house the application, willingness to engage with the mHealth app on a daily basis and ability to provide feedback. To minimise bias and provide true usability to the uninitiated user, participants involved in Phase I and II were excluded from participation. Initially, a sample size of 12 users was planned (as reflected in Publication 2, section 3.2). It was later discovered that a sample of 8-10 participants leads to the identification of up to 80% of usability problems (Kushniruk and Patel 2004). Eight participants commenced participation and six participants completed the study. The

participant information sheet and consent form for patients and family caregivers, are located in Appendix R.

Data collection

Participants reported their user experience using both qualitative and quantitative methods. First, participants completed a modified version of the MARS (included as a multimedia attachment to the online version of Publication 8 and located in Appendix S). The MARS (Stoyanov et al., 2015) was used to evaluate the application from the end-user's perspective. It assesses the quality of mHealth apps under four major categories each with their own mean scores (Stoyanov et al., 2015):

- Section A Engagement: entertainment, interest, customisation, interactivity, target group;
- Section B Functionality: performance, ease of use, navigation, gestural design;
- Section C Aesthetics: layout, graphics, visual appeal; and
- Section D Information: accuracy of application description, goals, quality of information, visual information, credibility, evidence base.

Two additional sections ask participants about subjective quality, expected use, change in behaviour, attitudes and knowledge on a 5-point Likert scale.

Participants were provided a paper copy of the modified MARS to return via self-addressed envelope or soft copy to complete electronically and return via email. Participants were able to choose their preference. Secondly, participants were interviewed by phone using a semi-structured interview schedule (Appendix T) to elicit feedback on the perceived impact of the app on heart failure self-management.

Further research regarding the MARS tool has emerged during the time of this research. A user version of the Mobile Application Rating Scale (uMARS) became available (Stoyanov et al., 2016) after the study design for this research was finalised. Consequently, patients in this research were given a version of the MARS modified by the research team for this context, and the uMARS was not used. Nevertheless, it was possible to compare the app quality from this research with comparable apps on the consumer app stores published by Masterson Creber et al. (2016). This is explained in Publication 8 (section 6.4).

Data analysis

Descriptive statistics were used to summarise the quantitative results. The mean and standard deviation for each subscale plus a composite total score was calculated using Microsoft Excel.

Interviews were transcribed verbatim and thematically analysed using Braun & Clarke's process (Braun & Clarke, 2006). The six steps that were followed include:

1) Familiarisation with the data;
2) Generate initial codes;
3) Search for themes;
4) Review themes;
5) Define and name themes; and
6) Produce a report.

Detail on how thematic analysis of interview transcripts was conducted in Phase III is found in the methods section of Publication 8 (section 6.4).

3.4.4 Phase IV: Process evaluation

The objective for Phase IV was to evaluate the co-design process of developing the mHealth application from the perspective of the multiple stakeholders involved. Specific research questions were:

1) What was the experience of clinicians, patients and family caregivers engaged in the co-design process; and
2) What were their perspectives on the design outcome.

To evaluate the co-design processes enlisted to develop the mHealth app, semi-structured interviews were conducted with participants. The 'Rose, Thorn, Bud' technique and a brainstorming session with post-it notes were conducted and data analysed using a modified affinity diagram. Phase IV study procedures are explained in the next sub-section and detailed in Publication 9 (section 7.2).

Participants

Participants who completed Phase III were invited to participate in the evaluation. Seven clinicians, 3 patients and 1 family caregiver participated.

Data collection

Interviews were conducted with participants between February and May 2018 and were predominantly conducted in person on the hospital campus. Three participants responded via email exchange due to time and geographical limitations. Using the 'Rose, Thorn, Bud' technique from

Design Thinking (Luma Institute, 2012), participants were asked to respond to the question '*How did the app design process go?*'. As per the data collection procedures for the clinician stakeholder group reported in Phase I, participants responded by writing directly onto specific-coloured post-it notes to reflect what worked, what didn't work and what could be done better next time. Figure 12 represents the instructions to participants.

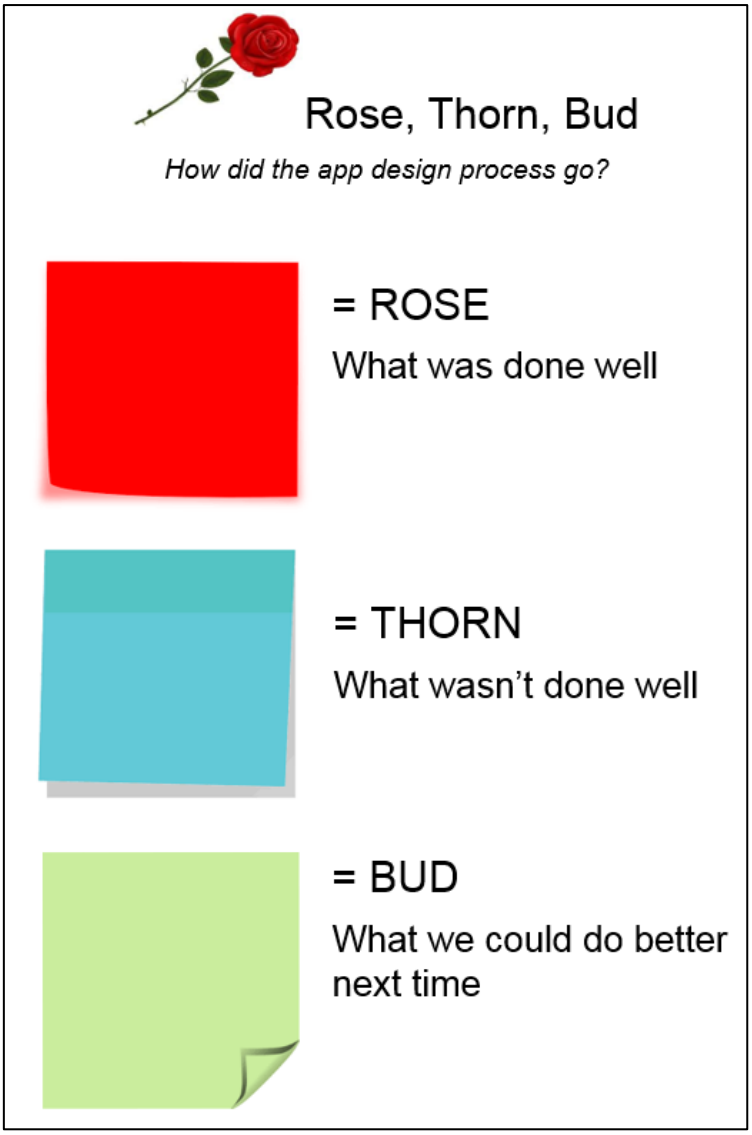


FIGURE 12. ROSE, THORN, BUD TECHNIQUE - INSTRUCTIONS FOR PARTICIPANTS

During the interview, participants were prompted to respond to their experience of participating in development activities. Figure 13 was the visual representation of stakeholder participation in the co-design process. This was used during the interview to remind participants of their involvement

especially considering stakeholder participation varied and the development journey took several months. Bold text represents the research outputs from each design activity.

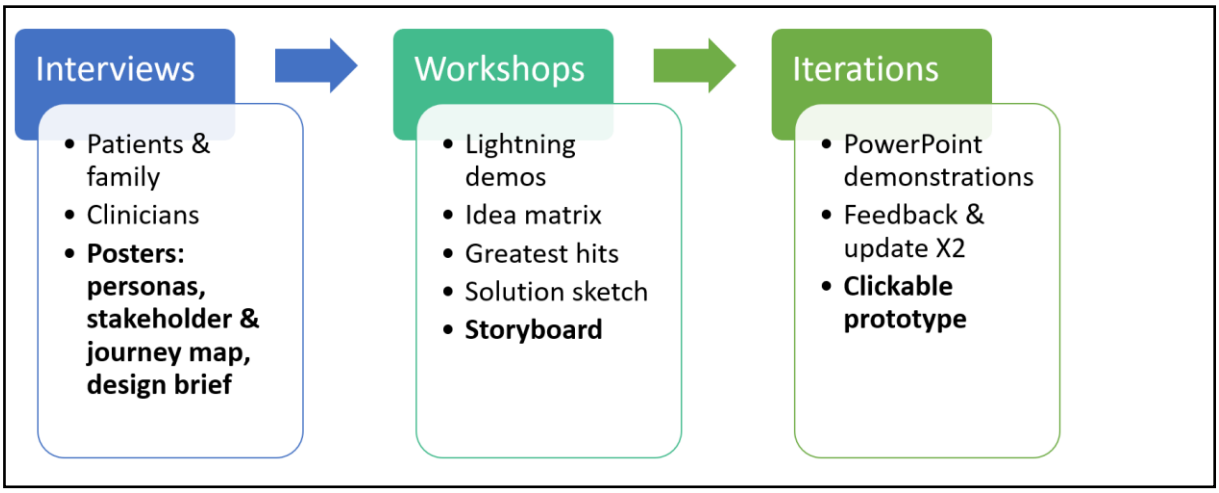


FIGURE 13. STAKEHOLDER INVOLVEMENT IN THE CO-DESIGN PROCESS WITH THE PHASED OUTPUTS REPRESENTED IN BOLD TEXT

Next, to gather perceptions on the design outcome, participants responded to two more questions by writing on post-it notes. The questions were; *What do you think of the app?* and *Would you use or recommend the app?* Probing questions facilitated explanations of their responses to capture rich, detailed information about their thoughts of the app, specifically considering the healthcare context in which the app would be implemented.

Data analysis

An affinity diagram, modified for application as a Design Thinking technique (Weprin, 2016), was used for analysis of the data. Detail on the technique is provided in the methods section of Publication 8 (section 6.4).

3.5 Ethical considerations

Minimal risk ethical approval was granted by the University of Tasmania's Social Sciences Human Research Ethics Committee on March 31, 2017; Reference number H0016365 (Appendix U). An organisational letter of support to conduct the research was written by Dr Jose Aguilera OAM, Adjunct Professor, Director of Nursing & Clinical Services, St Vincent's Private Hospital Sydney. Ethical clearance was given by the Practice Development & Research Council on behalf of the site, St Vincent's Private Hospital Sydney on April 10, 2017 (Appendix V).

The University of Tasmania and St Vincent's Private Hospital Sydney approved the ethical amendment to add St Vincent's Clinic as a recruitment site. A final ethics report was submitted to the ethics committee at the University of Tasmania in February 2019, reporting that no incidents or ethical issues arose during the research.

Ethical conduct

Research was conducted as per the National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2007b) and the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council, 2007a). These resources provide guidelines and frameworks for the responsible practices, and ethical conduct of research conducted with human participants. In this research ethical conduct included, but was not limited to the following:

1. Perceived conflicts of interest were disclosed. The role as senior ward nurse as well as student researcher was disclosed to participants as per National Statement 5.4.3 (a). Participants were informed of the research student's role as a clinical nurse at the hospital in which the research took place. The ethics application reported that there was no conflict of interest affecting either the individuals' interests/responsibilities in carrying out the research or the institution's interests/responsibilities in carrying out the research. As per the NSW Health Guidelines for Research Governance in NSW Public Health Organisations (p.17, Office for Health and Medical Research, 2011) item 4.3 a single organisation 'frequently fulfils the role of both employer and host for a given research project'. As a senior nurse, the student researcher was supported by the hospital executives to conduct research in her area of clinical practice – cardiology nursing. All research activities were carried out in professional dress (not in the hospital's nurse uniform) with university identification visible, outside of scheduled nursing shifts.
2. Ethical conduct was monitored. The research was conducted under the direct supervision of experience researchers, the PhD supervisors. Located on site during data collection, the Chief Investigator, Dr Kim Walker, was available to assist with any questions or concerns.
3. Appropriate participant consent was obtained as per the guidelines in Chapter 2.2 of the National Statement. Participation was voluntary and based on sufficient information and an adequate understanding of the proposed research. An information sheet and consent form were used to provide potential participants with necessary information about the study. The aims of the research were communicated and what we were asking of them in terms of

participation was made clear. Participants were also aware they would not directly benefit from the research, but the research outcomes would be accessible should they wish to review them. Written informed consent was established after procedures were explained and prior to research participation. Patient and family caregiver participants were provided the appropriate participant information sheet. Participants were encouraged to contact the research team by phone or email if they encountered problems or had questions about their participation. For Phase III, app use was self-reported by participants themselves as no ethical approval was granted to collect usage data. No usage data or content was collected or stored outside the test environment.

4. The research was designed to minimise the risk of harm and discomfort to participants. Participants were not recruited if they were highly dependent on medical care, had a cognitive impairment or unable to understand the information sheet. For the usability study conducted in Phase III, it was made clear to participants (information sheet, consent form and verbally) the application does not substitute or add to existing care provided by St Vincent's Private Hospital Sydney, their cardiologist, nursing staff and/or the out-patient Heart Failure Service at St Vincent's Hospital; it is merely an evaluation of the user-experience of interacting with the application interface. Participants were instructed to continue with their regular care regime in collaboration with their healthcare providers.
5. Participant bias was minimised. Potential participants self-selected to partake in this research and were not approached directly during the recruitment phase, therefore, mitigating the possibility of coercion or bias. Participants involved in Phase I and II were not eligible to participate in the usability study conducted in Phase III to minimise bias and reflect the true usability of the app to the uninitiated user.
6. Appropriate data storage processes were followed. Electronic data is kept in a password protected repository specifically assigned to research data and hard copies are kept in a secure cabinet in the locked office at the University of Tasmania's Research Office. Any identifiable information collected remains confidential and only the named researchers have access to it. The electronic repository is overwritten with the assistance of the IT department. All data will be held for 5 years from the date of the first publication. Then, hard copies will be deposited in an approved confidential waste receptacle for disposal and electronic data permanently deleted.

Classification of stakeholder participation

The term 'participants' is used broadly in the National Statement. The research plan was carefully designed in considering the various stakeholders to be involved and classifying who, and who were not, research participants.

Clinicians engaged in the research were classified as investigators and named on the ethics application. The investigator role included maintaining and safeguarding the confidentiality of data whether written, electronically recorded or generated or acquired by the team, and also actively supporting the team members involved in the research. Patients and family caregivers, however, were classified as research participants to align with the research integrity principles outlined in the National Statement.

Intellectual property

As this research was conducted by a student the intellectual property remains with the student. Investigators, participants or other stakeholders cannot benefit financially from involvement in the research even if, for example, knowledge acquired from the research proves to be of commercial value. The software partner chosen for this research was able to, and therefore assigned, intellectual property of the newly developed app to the student researcher at the completion of the research. This was not the case for other software companies who provided quotes for the app build. Most companies were unable to transfer intellectual property to the student researcher due to a number of reasons including proprietary technology.

3.6 Chapter 3 summation

In this chapter, the methodological approach and the study procedures were explained. The rationale behind using the Design Science Research Cycles, Design Thinking process and co-design principles was described, as we aimed for a well-designed mHealth app which would address the needs of stakeholders and be relevant to the clinical environment. A four-phased pragmatic and person-centred study design was used to address four research objectives, incorporating a variety of data collection and analysis processes. Importantly, the involvement and engagement with specific stakeholders in each phase was highlighted. Finally, the ethical implications of the research were identified.

The next chapter (Chapter 4) is the first chapter which reports the research phases. The chapter presents research Phase I where various stakeholders were interviewed to explore perspectives on heart failure self-management prior to app design and development.

Chapter 4 : Phase I - Stakeholder perspectives prior to app design and development

Understanding the experience and perspectives of various stakeholders involved in heart failure self-management is the focus of this chapter. This segment of the research, conducted prior to the design of the app, uncovers experience data from two stakeholder groups: first, patients and family caregivers; and second, clinicians regularly involved in heart failure care. Subsequently, Publication 3 represents the patient and caregiver experience and Publication 4 presents the clinician experience.

Phase I is particularly aligned to the 'inclusion' principle of co-design where various people with different types of knowledge are included in the process whether it be lived experience, professional or specialist expertise (Blomkamp, 2018b). Findings from the scoping literature review (Publication 1, section 2.3) indicated the importance of participatory and user-centred design processes in the pre-design phase of mHealth development for chronic conditions. Commonly described as a 'needs assessment' or 'requirement analysis' in the literature, these activities were often conducted with both healthcare consumers and healthcare providers. They were conducted within a specific healthcare context prior to any design work, to gather a multi-person view of a healthcare challenge which would later benefit the design.

Two highly significant Design Thinking stages are reported in this chapter: first, the 'empathise' stage where the experience data were uncovered, and second, the 'define' stage where the experience data were represented. These two stages are reported together in this chapter as presented in Figure 14.

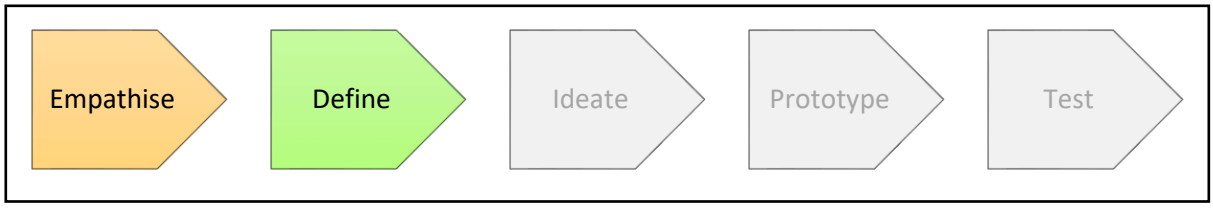


FIGURE 14. EMPATHISE AND DEFINE STAGES OF THE DESIGN THINKING PROCESS

The research outputs reported in this chapter were essential inputs for the design and development of the mHealth application, to be reported in subsequent chapters. The publications describe how the traditional qualitative method of interviews can be adapted using creative techniques from Design Thinking. These techniques facilitate the visual representation of experience data in the

define stage, as it acts as input to the ideate stage described in Chapter 5, where stakeholders are asked to work together in design workshops.

Chapter 4 is divided into the following sections:

Section 4.1 is the preface to Publication 3 which reveals the experience of patients and their caregivers in the context of heart failure self-management. The publication in part addresses Research Objective 1 as it describes the needs and perspectives of patients and family caregivers prior to the design and development of the app;

Section 4.2 presents Publication 3 - *Representing the patient experience of heart failure through empathy, journey and stakeholder mapping* published in the Patient Experience Journal in 2019;

Section 4.3 is the preface to Publication 4, which reports the experience and perspectives of clinicians as stakeholders involved in supporting patients and their family with heart failure self-management. It in part addresses Research Objective 1 in regard to the experience of providing self-management support from the perspective of the many multidisciplinary healthcare professionals in the health service;

Section 4.4 presents Publication 4 - *Partnering in Digital Health Design: Engaging the Multidisciplinary Team in a Needs Analysis* published in Studies in Health Technology and Informatics in 2018; and

Section 4.5 provides a summation on Chapter 4 explaining how it addresses Research Objective 1. Importantly, the research outputs are summarised as they act as input for Phase II activities.

4.1 Preface to Publication 3

Publication 3 presents the patient and caregiver experience of heart failure self-management. These are the findings from the empathise and define stages reported by a self-selecting group of healthcare consumers within the health service. The need to understand the experience of healthcare consumers prior to mHealth intervention design for chronic conditions is well documented (Gilbertson-White, Yeung, Mercer, Bartoczszyk, & Papke, 2016; Hallberg et al., 2014; Sánchez-Morillo, Crespo, León, & Foix, 2015). Consistent with the user-centred design methodology, early patient engagement is used to define the initial system requirements (Sánchez-Morillo et al., 2015) and this was well documented in the scoping literature review (Publication 1, section 2.3). The goal of including patient perspectives from the beginning ensures the design stems from the needs of the target user (Hallberg et al., 2014). For innovation processes more generally, the Design

Thinking process advocates for early empathic engagement with people knoweldgeable about, and most impacted by, a service, product or experience (Roberts et al., 2016).

Publication 3 illustrates that data and creativity can be merged to represent the diverse, complex nature of the patient experience. It is achieved with the use of three rapid design methods: empathy; journey; and stakeholder mapping. The three approaches are systematically described, the experience data is reported, and the method is evaluated for suitability to representing the patient experience.

As the publication focuses on the lived experience of heart failure self-management from the perspective of patients and family caregivers, the *Patient Experience Journal* was an appropriate journal to publish this work. The Patient Experience Journal is an international, multidisciplinary, open-access and peer-reviewed journal published in association with The Beryl Institute, focused on understanding and improving the patient experience. The publication contributes to the knowledge-base in two ways: on the patient experience of heart failure self-management specific to the context; and additionally, it expands on the methodological approaches to collecting and representing experience data for the purpose of designing healthcare interventions.

The citation for the publication is:

> Woods, L., Duff, J., Roehrer, E., Walker, K., & Cummings, E. (2019). Representing the patient experience of heart failure through empathy, journey and stakeholder mapping. *Patient Experience Journal*, *6*(1), 55-62. The publication is available at https://pxjournal.org/journal/vol6/iss1/8/

4.2 Publication 3: Representing the patient experience of heart failure through empathy, journey and stakeholder mapping.

See next page.

PXJ Patient Experience Journal
Volume 6, Issue 1 – 2019, pp. 55-62

Research

Representing the patient experience of heart failure through empathy, journey and stakeholder mapping

Leanna Woods, University of Tasmania, Australia and *St. Vincent's Private Hospital, Sydney, Australia, Leannaj@utas.edu.au*
Jed Duff, *The University of Newcastle, Australia Jed.Duff@newcastle.edu.au*
Erin Roehrer, *University of Tasmania, Australia Erin.Roehrer@utas.edu.au*
Kim Walker, *University of Tasmania, Australia Kim.Walker@utas.edu.au*
Elizabeth Cummings, *University of Tasmania, Australia Elizabeth.Cummings@utas.edu.au*

Abstract
Heart failure is a long-term condition requiring those affected to manage numerous self-care related activities. People with heart failure report multiple challenges accommodating self-care activities in their every-day life. The aim of this study is to (1) understand the experience of people with heart failure and their caregivers in the local patient population, and (2) visually represent these experiences to inform the design of a mobile health intervention supporting self-care. Seven patients and four family caregivers were interviewed using an empathic approach. Data was collected using rapid design methods including an empathy map to uncover patient and caregiver perspectives and a journey map to document daily self-care activities. Content analysis resulted in a needs and insights summary, a journey map and stakeholder map. The needs and insights are summarised in five themes; controlling, trusting, concerned, symptom- laden and accepting. Negative experiences - restlessness, breathlessness and urination – occurred overnight as visualised in the journey map. Overwhelmingly the spouse and general practitioner were the personal and professional stakeholders involved in self-care activities. Understanding the experience of people with heart failure was the first step in the creation of a patient-centred mobile health intervention. Rapid design methods such as the three presented in this paper can give voice to the patient experience, their frustrations, challenges and existing support structures in a clear, visual format to aid empathic design.

Keywords
Patient experience, patient- and family-centred care, qualitative methods, heart failure, self-care

Introduction

Self-care is seen as the key to heart failure management but the understanding of how to operationalise the concept remains inadequate. The literature on heart failure self-care predominantly focusses on knowledge and skills as enablers since effective self-care improves outcomes and addresses the healthcare burden of the condition.[1] However, living with heart failure is viewed by patients as a life-changing event[2] and the experience is expressed as being very challenging,[1] often with the presence of ambiguous symptoms.[3] The complexity of the patient experience poses challenges when attempting to advance care to improve clinical outcomes and quality of life.

The needs and views of patients and caregivers themselves are seldom included in the design of interventions for heart failure self-care.[1] Where experience information is considered it is broad and generic in nature which does not take into account the fact that perspectives differ with social, economic and geographical determinants of health and the accessibility, quality and affordability of health services. This context-specificity needs to be considered in future interventions for the condition[3] to improve patient-centred healthcare that meets the requirements of healthcare consumers. Advancing methods for capturing rich experience data for healthcare intervention design is needed.

The aim of this study is to (1) understand the experience of people with heart failure and their caregivers in the local patient population, and (2) visually represent these experiences. Visual representation of experiences provides critical insight for the design team in the development of a self-management mobile health intervention for this patient population. This paper reports research findings and discusses the suitability of empathy, journey and stakeholder mapping in representing patient experience.

Methods

A design thinking framework for innovation was used. Design thinking focuses on the human experience using empathy[4] to uncover contextual specifics as a novel approach to an existing, complex challenge.[5] Design thinking and other rapid design methodologies offer a set of tools that can help collect, analyse and incorporate experience into the design of health interventions.[5] Here, three rapid design methods generated from a single interview with each participant, are presented.

Semi-structured, face-to-face interviews were conducted with seven patients with heart failure and four family caregivers. Recruitment was via self-selection from recruitment posters and flyers displayed in common areas within the health service; an acute private hospital and co-located out-patient clinic in Sydney, Australia. Written informed consent was established prior to participant interviews which were conducted between May and August 2017. Ethical approval was granted by the University of Tasmania and the health service.

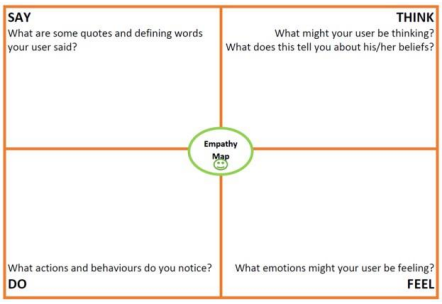
Interviews followed an interview schedule using empathy as a means to uncover participant experience data. An empathic approach to design, as defined by Wright & McCarthy [6 (537-8)] begins with a 'rich understanding of people's experiences, dreams, expectations, and life contexts'. It is achieved through a meaningful emotional encounter between researcher and participant using dialogue and responding empathically.[6] The approach facilitated discussions that were highly flexible, allowing participants to speak of their experiences, share stories, reflect on healthcare interactions and raise the most salient issues in their daily lives. To represent research findings, the response to the participant experience data was the formation of a needs and insights summary uncovered from empathy map content, along with a journey map and stakeholder map. Each of these three processes are detailed below.

Needs and Insights

Data collection during the interview involved the use of a four-quadrant empathy map as a way to document what was *said*, what the participant was *thinking*, what they *do*, and how they *feel*[7] (Figure 1). The term 'user' was derived from the common application of empathy mapping in market research. Interview questions focussed around overall perceptions of health, how health is managed at home and involvement of others.

Following the interview, needs and insights were elicited via content analysis: *Needs* are verbs which relate to activities or desires and *insights* are interesting or surprising realisations often uncovered from data merged from two or more quadrants within the empathy map.[7] The individual needs and insights were combined to produce

Figure 1. Modified empathy map[7] used in participant interviews



themes in response to having, or caring for someone with, heart failure. Content analysis revealed the dominant characteristics. A table was created listing each dominant characteristic and described the needs and insights associated with this patient category (Table 1).

Journey Map

The concept of customer journey mapping comes from the business world in respect of better understanding how customers interact with a product or service.[8] In planning for this study, it was adapted and simplified for use in health to capture a day-in-the-life of healthcare consumers. Patients and caregivers were asked to list and comment on the self-care activities they carried out over a usual 24-hour period at home, starting from waking up in the morning through to the following morning. The interviewer documented activities and emotional responses (verbatim quotes and perceived emotions) either side of a long line drawn on A4 paper representing the 24-hour period. Frequently reported self-care activities were clustered alongside other participant responses, and the emotional responses within each cluster were thematically analysed and summarised. A poster was created representing the main activities conducted in the morning, afternoon, evening and overnight period. Alongside each activity is a defining quote and corresponding emotional response either negative, positive or neutral (figure 2).

Stakeholder Map

Content related to other persons involved in self-care activities was extracted from each participant's empathy map and journey map. This included who and to what extent that person was involved. In creating the visual representation of these findings and to differentiate the two main stakeholder groups, a colour-code was applied to personal stakeholders (green) and professional stakeholders (blue). The extent to which a stakeholder was involved in self-care activities was represented through the size of the circle corresponding to that stakeholder, i.e. the

Table 1. Needs and insights of patients with heart failure

Dominant characteristic	Needs	Insights
Controlling	• Tracks weight • Updates written medication lists • Carries medical file to appointments	• Frustration with treatment changes • Misplacing documentation and poor information sharing is a stressor • Caregiver: Likely to support structured/organised approach
Trusting	• Fosters interpersonal relationships with healthcare team • Pursues reassurance and support • Seeks tips and tricks from healthcare team	• Respects and trusts doctors and nurses' recommendations • Avoids detail on heart failure and treatments • Caregiver: Fosters relationships and rapport with healthcare team
Concerned	• Reassurance from others • Strategies to manage anxiety • To be informed 'what to do'	• Poor communicator and planner when unwell • Sub-optimal decision making • Caregiver: Likely to advocate and seek care due to feelings of hopelessness
Symptom-laden	• Quality sleep • Know symptom self-management support strategies • Education regarding link between treatments and symptom management	• Feels controlled by symptoms • Frustrated and exhausted by the presence and severity of symptoms • Caregiver: May feel useless or experience grief; not identify deterioration due to ongoing severe symptoms.
Accepting	• Focus on the 'big picture' including striving for good quality of life • Work/hobbies/nature contribute to wellness • Seeks community engagement and interpersonal relationships	• Suboptimal understanding regarding details of heart failure and self-care • Frustrated by poor communication between healthcare providers • Caregiver: Likely to be insightful, loving and grateful; strives for balance between caring duties and living their own life

larger the circle, the more involved the stakeholder (Figure 3).

Results

Seven patients (4 female, 3 male) and four family caregivers (3 male, 1 female) chose to participate. Two married couples and a parent-child pair were included in this sample. The age range of patient participants was 51 to 89 and family caregivers was 56 to 82. Five participants were from metropolitan Sydney and six were from a rural area or another city. The experience of heart failure from the perspective of patients and their family caregivers is represented in a needs and insights summary, a journey map and a stakeholder map. These findings are detailed below.

Needs and insights

Consistent with the design thinking methodology, the needs and insights elicited from empathy map content were collated to five patient categories each with a dominant characteristic (Table 1).

For patients exhibiting *control* over their health information their needs consisted of keeping updated medical documentation with them in a folder or diary, tracking their daily weight and step count, stating 'I want facts and figures; I know where I stand'. Patients were likely to become frustrated with changes to treatment plans and stressed by misplacing documentation; 'My diary is my external memory storage device. If I lose it I go into panic mode'.

Trusting others in the heart failure journey comprised the need for ongoing, interpersonal relations with reassurance and practical support from healthcare team members. While patients respected treatment recommendations provided by their healthcare team, suboptimal understanding may follow; 'I don't try to understand; these blokes get paid enough to know. I'm happy enough they're fixing me up.'

For patients constantly *concerned* and worried about their condition, reassurance, being informed about 'what to do' and strategies to manage anxiety, are important. Due to ongoing anxieties for example, demonstrated by the

comment 'I worry about everything. I hope everything's alright', these patients are unlikely to identify, communicate and plan self-care due to the overwhelming concern impeding their decision-making capabilities.

Similarly, those with many interacting *symptoms* need education on symptom self-management support strategies. For example, proper functioning requires quality sleep as one participant explains, 'Things are getting beyond me'. Insights from patients with many symptoms include exhaustion by the presence and severity of the symptoms experienced, limited ability to attend to daily activities and frustration that symptoms can't be adequately treated by their healthcare team.

The final category was patients who are *accepting* of their condition. These patients focussed on striving for quality of life through leveraging what makes them happy such as hobbies, work or getting out into nature, stating 'I have to play the cards I've been dealt…I try to find ways to make life enjoyable'. Insights from this patient category include suboptimal understanding regarding the detail around self-care treatments. They also expressed frustration regarding the poor communication of medical information between health service providers.

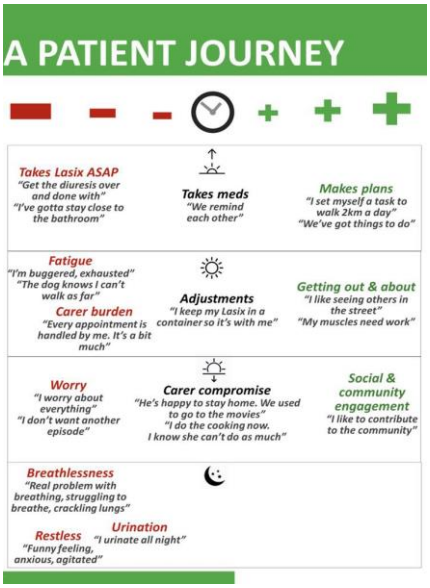
Family *caregivers'* response to each patient group varied. Some caregivers mirrored the traits of the patient, supported self-care and built rapport with the healthcare team, while others struggled for a balance between caregiving and living their own life. Some reported feelings of helplessness and feeling overwhelmed; 'It's a bit much'. Advocacy came in the form of caregivers seeking medical assistance on behalf of the patient feeling they were 'hesitant to make a fuss'.

Journey map

The patient and caregiver journey over a 24-hour period is represented by a list of common self-care activities carried out in the morning, afternoon, evening and night alongside the emotional response to these activities (Figure 2). A negative emotional response is represented in red on the left-hand side of the figure while positive emotional responses are represented in green on the right-hand side. Neutral responses are represented in black text.

The *morning's* activities consisted of taking medication (particularly diuretic medications which cause the kidneys to produce more urine) and planning the day. Organising, swallowing and remembering to take morning medications were reported by the patient and caregiver by the comments; 'Have you taken your tablets?' and 'Mum takes her tablets herself'. Taking diuretics was known to cause inconvenient diuresis associated with delays in planning their day; '[I must] get the diuresis over and done with. Can't plan the day until the diuresis is complete'. The inconvenient effects of the morning diuretic medications

Figure 2. Journey map: Daily self-care activities, caregiver involvement and scaled emotional response



was noted by a caregiver; '[We've] gotta get the effect out of her'. Participants reported their positive attitude and sense of control to plan for daily activities, like exercising; 'We've got things to do. We chat about what we're doing' and 'I set myself a task walking 2km a day'.

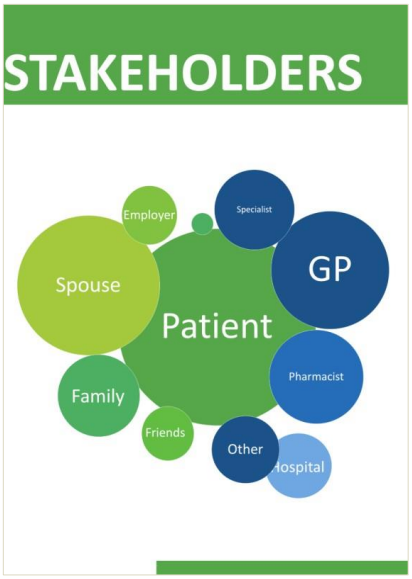
In the *afternoon*, positive participant experiences were demonstrated through physical activity and getting out of the house; 'I like seeing others in the street'. Adjustment to a new level of capability, was demonstrated in the tennis example; 'If a ball comes in reach, I whack it' and walking the dog; 'The dog knows I can't walk as far'. Condition-related activities such as attending medical appointments and filling scripts at the pharmacy often occurred in the afternoon. Navigating these activities together with local health staff was noted; '[I have] two chemists [in town]; if one is out of stock they call the other and get it sorted'. Planning for these afternoon activities was noted in carrying lunchtime medications with them for the day and doing groceries 'after 3pm when the school kids are working to help put groceries in the car'. Fatigue was commonly reported in the afternoon through the patient statements 'I'm buggered, exhausted' and 'I can't keep my eyes open'. Similarly, family caregivers reported specific carer-related challenges and concerns predominantly in the afternoon. Statements such as 'every medical procedure is

handled by me - It's a bit much'; 'it's frustrating when mum doesn't give me warning [that her scripts are running low]'; and 'should I call the doctor or not?' illustrate the caregivers' challenges and concerns.

In the *evening,* positive activities for patients and their caregiver often involved community and social engagement; 'I play bridge with friends' and 'I like to contribute to my community'. For others however, exhaustion caused a decrease in social activities; 'The sick person is happy not to see people. We used to go to the movies [but not now]'. The compromise of the caregiver was noted through contributing more around the house with one participant commenting 'I'm aware she struggles, can't do as much' while another commented on doing more cooking. Reports of anxiety were higher in the evening exampled by the patient comment; 'I worry about everything. I don't want another episode', requiring medication at times; 'For a crisis, if stressed or anxious, she takes a Valium [diazepam] before bed'.

The *overnight* period presented only negative emotional responses from participants focused on breathlessness, restlessness and the urge to urinate. Participant comments demonstrated anxiety, agitation, breathlessness, crackling lungs, inability to lay down flat and constant urination. Caregiver responses focused on concern for their loved one through the comments 'I listen to her struggling for breath', 'He's gasping for air' and there's 'nothing more comforting to me than waking up and hearing her breathing beside me - I always worry'. Family caregivers reported sleep disturbance; 'It's annoying. I can't sleep'.

Figure 3: Stakeholder map: Heart failure related personal network (represented in green) and health professional network (represented in blue)



Stakeholder map

Personal stakeholders are represented in green with larger circles representative of more involvement in every-day life. Blue circles correspond to health-related stakeholders (Figure 3).

The spouse was the most involved *personal stakeholder*. The spouse was most likely to be the greatest support person, demonstrating love and commitment to the health of the person living with heart failure and contributing to housework. They were involved in medication, organising medical appointments, had insight into the patient experience and navigated caregiver challenges aiming for a balance between having their own life and assisting. Other family members were highly valued, but it was uncommon for them to be involved regularly in self-care activities. A child caregiver was actively involved for a widower patient while some didn't see their family at all. Friends provided a social outlet and were not involved in self-care activities. Friends 'don't understand' heart failure nor see them as 'physically ill' which contributed to omitting heart failure-related discussions in the social setting. Furthermore, friends recommending alternative medical treatments frustrated participants at times. Employers were only relevant for a few participants while some discontinued paid employment for health reasons. Nevertheless, many told stories of their previous professional roles, speaking positively of their contribution to the workforce reflecting a strong work ethic. Financial pressures due to stopping work was a common research finding, as well as balancing paid work with caregiver responsibilities. With many participants seemingly community minded, other stakeholders were distantly involved such as the church community, neighbours and volunteer organisations.

In relation to *professional stakeholders*, the most involved was the general practitioner (GP). GPs were reported as being accessible, helpful, providing personalised care and an initial contact point for health-related concerns. Management of blood thinning medication (warfarin) with the GP however, was considered burdensome. Specialists, namely cardiologists were highly respected, set treatment and medication plans but were less frequently involved than the GP. Medication changes were a reported cause of stress for many participants and negative encounters with specialists were not forgotten by participants many years on. Respecting their experience and instructions were common themes alongside not needing to understand details. Pharmacists were regularly involved, often on a

weekly basis offering helpful advice, providing education and assisting with medication variations. Visiting the local pharmacy was a positive weekly or fortnightly event often associated with an outing, walk and opportunity to talk with others in the community.
A physiotherapist was involved with one patient, positively reflecting on a supervised exercise regime. The freely available multidisciplinary heart failure service was appreciated and considered accessible through phone calls to the nurse practitioner, but infrequently accessed in this participant sample. Many participants disliked the in-patient experience. The health system was commented on by a handful of participants. They expressed disappointment with the poor collaboration between health professionals stating that 'some doctors don't have each other's mobile numbers' and frustration regarding the lack of connection of information between health services especially for rural patients. Phlebotomists, paramedics and palliative care specialists were briefly mentioned.

Discussion

The research findings have been presented in three forms each representing a different component of the patient and caregiver experience. An empathic approach requires learning the needs of others[6] with the user perspective a valuable asset to identify the *actual* needs rather than the *perceived* needs of patients.[1] Using this approach, much of the findings regarding the patient and caregiver experience regarding heart failure self-care is consistent with three recent systematic reviews on the topic[1-3] but also adds important context-specific details relevant in this population. First in this discussion, the patient experience data is compared to the wider literature on heart failure and self-care practices. Second, the creative representation process is critiqued for suitability of use in intervention design.

Needs and insights

Heart failure self-care can be seen as a lifestyle adaptation focused on maintaining independence and quality of life.[2] Harkness et al[2] discovered that many patients accepted the possibility of maintaining a good quality of life with heart failure, however this process involved the re-evaluation of what was truly valued by them as individuals.[2] In this study, this was observed in the execution of self-care activities throughout the day, with patients and caregivers seeking a balance between sickness and wellness. Patients accepting of their condition particularly demonstrated this capability.

Further to *knowledge* as a recognised need in this patient group, applying this to every-day life remains challenging. Many patients from previous studies lacked the basic knowledge to conduct self-care effectively.[3] Knowledge deficits particularly related to medication, diet, fluid management and appropriate help-seeking.[3] Even when patients understood self-care recommendations, the real challenge was overcoming the difficultly of conducting self-care in the context of day-to-day life with fluctuating symptoms.[9] This was consistent with the insights uncovered in the current study specifically for symptom-laden patients whereby symptoms became an exhausting interruption to the daily routine. As important considerations for intervention design, the literature reports promoting self-efficacy, ongoing learning and facilitating adaptation to life patterns[1,3] to facilitate positive patient outcomes[3] in self-care.

Journey

Journey map findings emphasised the daily challenge of integrating self-care recommendations and heart failure knowledge into every-day life.[2,3] Once again knowledge reappears as a common enabler/barrier from the literature on daily activities carried out by patients with heart failure. Knowledge gaps affect the capacity to engage in specific self-care activities like salt reduction, medication adherence, weight monitoring and physical activity resulting in confusion, delays in care seeking and uncertainty about the future.[1] Further, terminology misconceptions about 'sodium' and 'salt',[3] challenges with meal preparation and issues with grocery shopping have been uncovered in previous studies.[1,2]

Nonetheless, patients with heart failure have demonstrated the ability to learn from previous experiences to develop intentional strategies in their self-care activities.[2] These learned experiences were evident through examples within the journey map, for example, the early morning administration of diuretic medications to lessen their effects during the main part of the day. Patients have also learned how to pace their daily activities and optimise their ability to do physical activity through modifying their daily activities.[2] This was consistent with participants in the current study planning their day in the morning, then re-evaluating activity throughout the remainder of the day based on fatigue and breathlessness. The journey mapping revealed that this ongoing 'juggle' to balance self-care and daily activities[1] has been shown to become a normal part of a patient's daily routine.[2]

Stakeholders

The research findings concur with previous studies; family caregivers are heavily involved and this can be tiring for them. Overall, caregivers are seen to facilitate adherence and foster independence,[1] assisting on an everyday basis through organising medications, buying groceries, preparing meals, monitoring symptoms and navigating the healthcare system.[2] Caregivers have detected variations in the patient condition which the healthcare professional and patients themselves didn't seem to identify.[1] Nevertheless, negative feelings of social isolation, distress, fatigue and ill preparedness of caregivers have been demonstrated leading to recommendations to increase

support for this stakeholder group.[1] Daily caregiver activities were similar in the current study and emotional responses to these activities uncovered equally challenging themes in relation to navigating the healthcare system, fatigue and distress.

Participants reported interacting with their GP more frequently than noted in the literature. The review by Harkness et al[2] referred to physicians as the main healthcare professional involved for patients who reported increased vigilance in symptom monitoring and adherence because of feelings of anxiety, fear of dying or fear of hospitalisation. Patients from previous studies reported uncertainty in developing a relationship with their primary healthcare professional.[2] Further, physicians tended to focus on clinical indicators rather than how the patient 'felt' within themselves which was not necessarily shared with their physicians.[3] This participant group predominantly spoke of positive interactions and open relationships with their GP which is the main differentiating factor to the aforementioned reviews.

Creative representation

As the number of people living with chronic conditions increases, creative service redesign is needed[10] to accommodate community requirements without compromising quality and safety. Alongside exploring ways to listen to consumers, their voice needs to be heard in healthcare forums.[10] Rapid design methods can be an important tool to capture and incorporate the patient experience in redesign efforts. This practice can give voice to the patient experience, their frustrations, challenges and existing support structures in a clear, visual format. This research demonstrated they can be used successfully in heart failure self-care.

The strength of this approach is not the collection of the experience data but the use of visualisation techniques that help make the data meaningful. In the context of collaborative intervention design the visual representations disseminated the research findings beyond written data alone, widening accessibility to non-traditional audiences. In this case, the needs and insights summary, journey map and stakeholder map were presented in poster format to a diverse group of providers and consumers in participatory design workshops to develop a novel mobile health intervention for heart failure self-management.[11] The use of colour and short quotes added an emotional component to the journey map and the linear nature of time was reflected in the layout. Challenging patient experiences are easily identified in the journey map, emphasising for example, the negative emotional response to all health-related activities in the overnight phase, namely breathlessness, restlessness and urination. Similarly, the use of colour and shape emphasised the frequent involvement of the spouse and GP in health-related interpersonal relations in the stakeholder map. Previous research has shown patients with heart failure define self-care not only by the activities they conduct for their health but also their emotional response.[2] As a single tool, the journey map captured a more holistic participant experience, adding subjective information to common self-care activities.

Limitations

While common themes from this research study, the findings are not necessarily generalizable to the wider heart failure population. The impact of participant self-selection on the findings is a limitation of the study. Further, the inherent potential biases of the project lead (first author) in operationalising this qualitative, creative work is to be acknowledged. In the pursuit to completely understand this phenomenon, an observational study, designed to objectively detail daily activities might complement the self-reported data presented in this paper. However, this would impact on the rapid nature of the design methodology.

Conclusion

Current research on the experience of heart failure is two dimensional and doesn't provide us with enough contextual details to design effective patient-centred interventions to support self-care. Rapid design methods provide tools to gather the patient and caregiver experience within a certain context. The three tools used in this study allowed the identification of needs and insights, emotional responses to daily self-care activities and stakeholders in heart failure self-care. These rapid design methods allow researchers to incorporate the diverse and complex nature of the patient experience through merging data with creativity.

Acknowledgements

The research reported in this paper is supported by a St Vincent's Clinic Foundation grant and an Elite Research Scholarship provided by The District Nurses, Hobart, Australia.

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4.3 Preface to Publication 4

Publication 4 presents the findings from the clinician stakeholder group which complements the patient and family experience represented in Publication 3. It reports the research conducted in the empathise and define Design Thinking stages prior to mHealth design and development.

The importance of understanding the healthcare context prior to mHealth development was stated in the scoping literature review findings. Clinicians are stakeholders involved in supporting evidence-based heart failure self-management in the health system. It is important to understand the context in which clinicians provide care in same healthcare setting in which patients and family receive care.

Publication 4 therefore focuses on the perspectives of the multidisciplinary team who regularly provide healthcare to patients with heart failure who may use a mHealth app for self-management. Specific objectives were to gather perspectives on the current support for heart failure self-management and clinical requirements in planning for the app's implementation. As explained in the publication, using rapid design methods from Design Thinking allows the extraction of design implications. The publication concludes with a summary of the research outputs from this phase, as inputs for the upcoming multi-stakeholder design workshops in Phase II. The primary outcome was the design brief, but Publication 4 explains the decision to add the 'current care' summary elicited from this data set, to sufficiently represent clinicians' experiences and perspectives.

As the publication focuses on engaging with clinicians to plan for digital health design, the chosen journal for this manuscript was *Studies in Health Technology and Informatics*. The publication was associated with an oral presentation in the 26th Australian National Health Informatics Conference (HIC 2018) which occurred during July 30 - August 1, 2018 in Sydney, Australia. It was published online via open access through IOS Press in the series titled *Connecting the system to enhance the practitioner and consumer experience in healthcare*. The greatest contribution of this publication to the knowledge-base is the use of the rapid design methodology by clinicians to quickly gather provider needs in a busy clinical environment.

The citation for Publication 4 is as follows:

> Reprinted from Studies in Health Technology and Informatics, vol. 252, Woods, L., Cummings, E., Duff, J., & Walker, K., Partnering in Digital Health Design: Engaging the Multidisciplinary Team in a Needs Analysis, pp. 176-181, Copyright (2018), with permission from IOS Press. The publication is available at IOS Press through http://dx.doi.org/10.3233/978-1-61499-890-7-176

4.4 Publication 4: Partnering in Digital Health Design: Engaging the Multidisciplinary Team in a Needs Analysis

See next page

Connecting the System to Enhance the Practitioner and Consumer Experience in Healthcare
E. Cummings et al. (Eds.)

doi:10.3233/978-1-61499-890-7-176

Partnering in Digital Health Design: Engaging the Multidisciplinary Team in a Needs Analysis

Leanna WOODS[a,b,1], Elizabeth CUMMINGS[a], Jed DUFF[c] and Kim WALKER[b]
[a]*School of Health Sciences, University of Tasmania, Australia*
[b]*St Vincent's Private Hospital Sydney, Australia*
[c]*School of Nursing and Midwifery, University of Newcastle, Australia*

Abstract. Using participatory co-design methods and in partnership with consumers we have developed a mHealth application to support heart failure self-management. In the first phase of the research we conducted a needs analysis with clinicians. The objectives were to define the features to perceivably support self-management and the clinical requirements in preparation for its implementation as an adjunct to existing multidisciplinary care. Interviews were conducted using the 'Rose, Thorn, Bud' technique from Design Thinking together with a brainstorming session with post-it notes. Six sixty-minute interviews and one email exchange with seven clinicians produced 154 data points in total; 97 relating to self-management support and 57 to clinical relevance. Analysis of these data points resulted in design implications articulated in a design brief for use in subsequent co-design workshops. Our discussion focuses on a critique of the technique, which appears to be useful for this stakeholder group although concerns of adequately representing complexity emerged. This method was considered inadequately comprehensive for use in the needs analysis with patients and family. The authors encourage further research evaluating in-hospital processes for co-designed health technologies.

Keywords. Participatory design, co-design, healthcare professionals, needs analysis, requirements

Introduction

We have co-designed a mHealth (mobile health) application to meet the challenges of people living with heart failure to self-manage their condition. Our development followed a co-design and iterative process working together with local clinicians, patients and their families [1]. Participatory co-design amalgamates design tools with an alternative way of thinking, in order to bring healthcare staff and patients together for healthcare improvement [2]. The various methods of co-design and the many stakeholders potentially engaged in co-design processes means that co-design in healthcare is practiced differently [2]. The main critique of co-design is 'it simply takes too long' so accelerated methods are emerging [2]. This is especially significant when choosing a needs analysis method which would be efficient and effective for the clinical stakeholder group in considering their busy workloads. In the provision of safe, specialised heart failure care from a healthcare provider perspective, the novel

[1] Corresponding Author: Leanna Woods; Email: leannaj@utas.edu.au.

intervention needs to align with existing policies, guidelines and current healthcare delivery models. Ultimately, clinicians were deemed most appropriate to gather these needs to incorporate into the design.

The aim of this phase of the research was to conduct a needs analysis with multidisciplinary team members who care for people with heart failure, prior to the design of the mHealth application. Specific objectives were to gather information regarding self-management support features of the application itself and the clinical requirements in planning for the application's successful implementation. This paper reports and critiques the process of the nurse-led needs analysis conducted with clinicians.

1. Process

In this mHealth design project the lead researcher conducted face-to-face interviews with clinicians from a variety of clinical backgrounds, to gather information regarding their perspectives and opinions. The setting was an acute hospital campus comprising a public hospital, private hospital and out-patient clinic. Averaging 60 minutes in length, interviews were conducted on the hospital campus over a two-week period in August 2017 and included an overview of the project. Clinicians invited to participate were healthcare professionals providing regular care for patients with heart failure from specialised nursing, medical, and allied health backgrounds. See table 1.

Table 1. Clinicians participating in the needs analysis.

Nursing	Medical	Allied Health
Two Nurse Practitioners	Cardiologist	Physiotherapist
Clinical Nurse Consultant		Pharmacist
		Dietitian

Six of the seven interviews were conducted face-to-face with the seventh conducted via email exchange. Two broad questions were asked which aimed to uncover a) the perceived features for self-management support to benefit people with heart failure and b) the clinical requirements for the application to complement existing care.

1.1. Needs Analysis; Self-management Support Features

The first question asked of clinicians was; *How do we support heart failure self-management at our health service?* Using the problem framing technique 'Rose, Thorn, Bud' as a method for analysing challenges and opportunities [3], clinicians were asked to document their responses to the following question prompts; *what is done well*; *what is not done well;* and *what could be done better.* Initial coding by clinicians - by writing directly on red, blue and green coloured post-it notes - represented their opinions as positively, negatively or having potential to improve heart failure self-management, respectively. See table 2.

Table 2. 'Rose, Thorn, Bud' technique to gather clinicians' perceptions of heart failure self-management support, question prompts and corresponding colour code.

Rose, Bud, Thorn	Prompt	Colour-code
Rose	What is done well	Red
Thorn	What isn't done well	Blue
Bud	What could be done better	Green

Ninety-seven data points (responses) were collected from seven clinicians representing 30 positive, 33 negative and 34 as having potential. Data was transcribed

verbatim into a Microsoft Word table, colour-coded as per table 2, printed and grouped by colour. Working with the same colour, data points were assessed and placed alongside similar ones resulting in several clusters. Each cluster was labelled with a summary statement elicited from analysis of the responses contained within it. The summary statements were refined by the research team to accurately represent an overview of these findings.

Table 3 represents clinicians' perceptions of how heart failure self-management is supported in our health service and the associated 'design priority' for the application's development; to *leverage* what is done well, *address* what isn't done well and *expand* on what could be done better. Design priorities were verbs assigned by the research team in the practical application of this technique to the creation of digital health. A poster was generated containing these findings as a way of visualising the existing state of affairs and emergent patterns [3], prioritising discussion points for the next phase of the design; the co-design workshops.

Table 3. Support for heart failure self-management from the perspective of clinicians.

	What is done well	**What isn't done well**	**What could be done better**
Design priority	Leverage	Address	Expand
Examples	In-patient care; written educational information	Follow-up; connected care; regular education	Individualised care planning; medication management

1.2. Needs Analysis; Clinical Requirements

In the same interview session, clinicians were asked the question; *The application needs to be clinically relevant to our health service: How can we do that?* Clinicians were encouraged to think about the broader healthcare context in which the application would be implemented, including considerations for recommending an application for the purpose of self-management support. Thoughts and ideas were documented directly onto post-it notes by interviewees.

Fifty-seven clinical relevance data points were collected from seven clinicians. Using the same data analysis process reported above, data was clustered and each cluster was labelled with a summary statement representing its content. The findings were that clinicians believed it beneficial for the application to be a hub for evidence-based information specifically for educational purposes and using 'patient-friendly' language and visuals, include or track patient data, contain a tailored care plan with a focus on medication management and include the multidisciplinary team. These findings, together with the self-management support findings needed to merge to form a list of implications for design.

2. Design Implications

The main outcome of this work was to define the design priorities as input for the next phase of the research; conceptual design and iterative development of the mHealth application. Based on a total of 154 data points collected, together with a concurrent ethnographic study of patients and family members into their daily life with heart failure, the research team defined a brief representing design implications. See figure 1. The implications for design regarding heart failure self-management features were to; address

medication and symptom management challenges; involve some kind of self-care plan; and manage all stakeholders well. The design implications to ensure clinical relevance were; an evidence-based resource that would be useful, simple and easy to use. A poster containing the brief was later used in participatory co-design workshops as the mainstay in the applications' design and development.

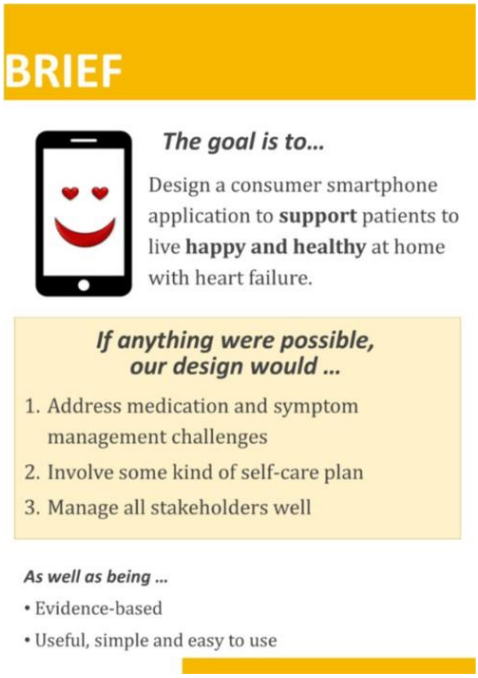

Figure 1. Poster representing the design brief.

3. Discussion

The co-design process in healthcare offers an opportunity to reflect on service experiences, identify design priorities and devise changes for healthcare improvement [2]. In a needs analysis with clinicians, capturing the current reality of care delivery from a variety of perspectives through the 'Rose, Thorn, Bud' technique was mostly beneficial but had its limitations.

Interviews were efficiently conducted on the hospital campus with no need for audio-recording or a lengthy data analysis process. The technique supported clinicians coding their own responses at the point of data collection. Clinicians easily understood the exercise and quickly provided responses, limiting their time away from patient care. Completing this task individually mitigated the challenge of getting all participants in the same location at the same time, as this technique is commonly executed in a group setting. With diverse perspectives, each clinician had the opportunity to express their thoughts and opinions, uncovering insights which otherwise might not have been uncovered using a single view point. As this was the first of many co-design interactions, rapport with the nurse-lead was established and was considered a beneficial priming

opportunity for the project as a whole. The interview provided a forum for clinicians' thoughts to develop prior to the time-limited design workshops where the conceptual design needed to be refined.

It is not clear however, whether the 'Rose, Bud, Thorn' technique accurately represented the complexity of self-management and its many interrelated factors. To mitigate this, we decided to represent the main findings of the self-management support question in poster format in addition to the design brief. It was later uncovered that providing this detail enabled workshop participants to understand the collective perspectives of clinicians more accurately while progressing through design activities. It is also to be noted that a concurrent needs analysis was conducted with patients and family members using a different methodological approach and is not the focus of this paper.

It was imperative to converge the findings into clear implications for design. Visual communication - through poster presentation - was useful in representing the abstract concepts elicited through the needs analysis, making a tangible representation which captured the complexity of clinicians' work and perceived impact on patients' self-management support within the health service. The goal was defined at the project's inception; to design a consumer smartphone application to support heart failure self-management. This needs analysis process clarified the design priorities as the team proceeded through the subsequent design activities. With the growing interest and support for co-design for healthcare improvement, the authors support the improved access to resources to engage with co-design activities, such as the recently published resource; Experience Based Co-design: A Toolkit for Australia [4]. Future research by this team will include a user-experience study to be conducted with a new group of volunteer patients and a process interrogation phase with all stakeholders.

4. Conclusion

A needs analysis was conducted to gather information regarding the requirements of a mHealth intervention to support heart failure self-management from the perspective of healthcare professionals. Clear, succinct design implications resulted from the analysis of 154 data points collected from seven clinicians representing the priority features for self-management support and the clinical requirements to be a safe, effective adjunct to existing multidisciplinary care. The 'Rose, Thorn, Bud' technique was simple and effective for use with this stakeholder group, while the research team used other methods in a needs analysis with patients and family members. Visually representing findings in poster format provided focus for the conceptual design activities succeeding this work. While initial feedback from participants support the efficient co-design processes of the interview techniques identified in this paper, evaluation of the effectiveness of this process to produce an effective application will follow.

Acknowledgements

We are grateful for practical training in Design Thinking provided by Ms Carol Harding (formerly Deputy Director, Australian Innovation Research Centre, University of Tasmania; currently carolharding.com.au). This project is supported by a St Vincent's

Clinic Foundation Grant and the University of Tasmania's Elite Research Scholarship funded by The District Nurses. No conflicts of interest.

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4.5 Chapter 4 summation

Chapter 4 presented various stakeholder perspectives of how heart failure is experienced. The rich, qualitative interview data from the empathise stage was necessary for the define stage where the data were represented in visual format. The publications in Chapter 4 addressed Research Objective 1: To explore stakeholder perspectives on heart failure self-management prior to app design and development.

Research outputs from Phase I reported in this chapter are summarised in Figure 15. Green represents research outputs from the patient and family caregiver stakeholder group and blue represents the clinician stakeholder group. The design brief (represented in yellow) was a composite of both stakeholder groups.

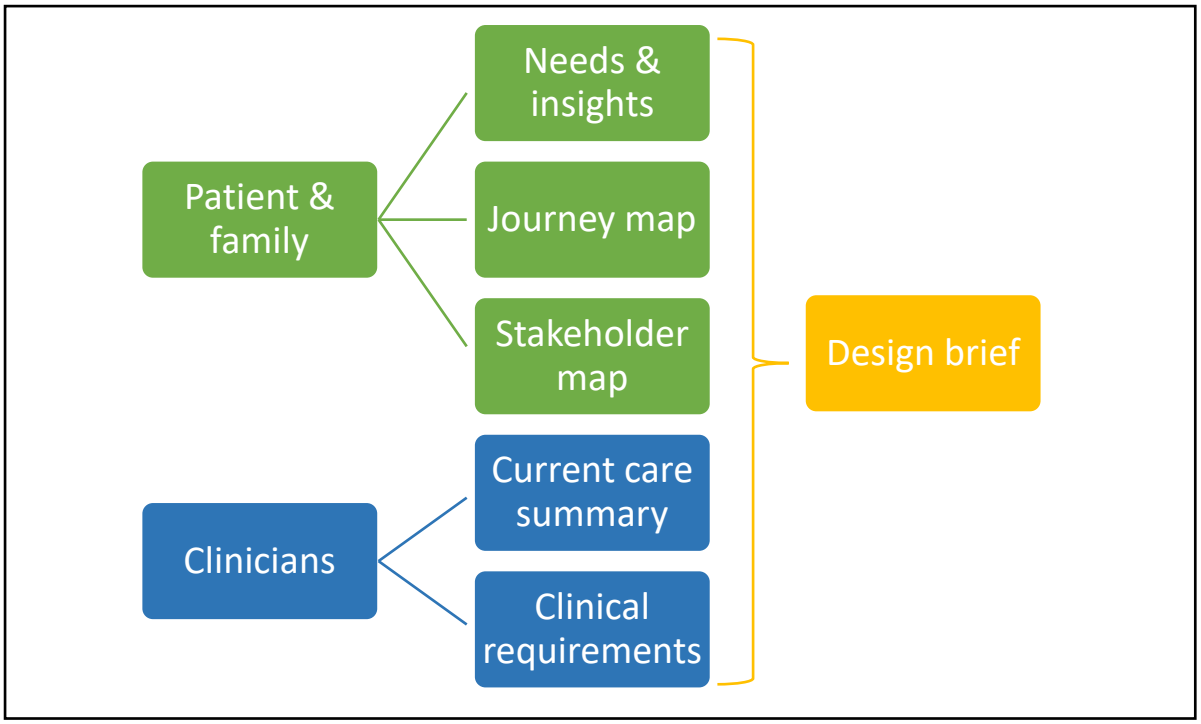

FIGURE 15. SUMMARY OF THE RESEARCH OUTPUTS ELICITED FROM TWO STAKEHOLDER GROUPS REPORTED IN CHAPTER 4.

Phase I research outputs are positioned in one or more locations in the thesis, as listed below:

- **Needs and insights:** section 4.2 and table 1 in Publication 3 (Personas were later created from the needs and insights summary in a process which is described in Chapter 5);
- **Journey map:** section 4.2 and figure 2 in Publication 3;
- **Stakeholder map:** section 4.2 and figure 3 in Publication 3;

- **Current care summary:** summarised in section 4.4, presented in table 3 of Publication 4 and displayed in poster format in Appendix W;
- **Clinical requirements:** listed in section 4.4 and presented in section 1.2 of Publication 4; and
- **Design brief:** section 4.4 and figure 1 in Publication 4.

Research outputs from Phase I served as inputs for the multi-stakeholder design workshops in Phase II, reported in Chapter 5. The strength of the research approach reported in this chapter was the clear and visual research outputs which made the experience data more meaningful for those involved in co-design. It gave voice to the frustrations, challenges and support structures based on the premise that interventions to support heart failure should incorporate the *actual* needs, rather than the *anticipated* needs of patients (Clark et al., 2014). For clinicians too, their perspectives on current healthcare delivery were expressed. Regardless of the stakeholder group, the research outputs served as accessible research data for later research phases in two ways. First, the visual format meant the posters were likely to be understandable by, and therefore inclusive to, a wide variety of people likely to be involved in a co-design process. Second, the perspectives of patients and family caregivers were available to be referred to in future research phases as we aimed for a user-centred design which was aligned to the needs of patients. This was especially important as we were unsure how many patients and caregivers would attend the workshops and subsequent development activities.

Research activities reported in this chapter also facilitated the formation of the design goals and design implications. This was reflected in the form of a design brief. See boxed text below for a recapitulation of the design brief, which is followed by a comparison of stakeholder perspectives in defining the components of the brief.

Design brief

The goal is to…. Support patients to live happy and healthy at home with heart failure.

If anything were possible, our design would….

1. Address medication and symptom management challenges,
2. Involve some kind of self-care plan, and
3. Manage all stakeholders well.

Both stakeholder groups unanimously agreed that the goal for the intervention would be to ‘support patients to live happy and healthy at home with heart failure’ through the development of a

smartphone app. The design implications, however, were defined through the combined priorities expressed by both stakeholder groups.

The first design implication was to address medication and symptom management challenges. While patients described the frequency and severity of heart failure symptoms (evidenced in the journey map, and needs and insights summary), clinicians reported the need to focus on medication management to treat the symptoms that patients experience.

The second design implication was to involve some kind of self-care plan. Interviews with patients and their caregivers uncovered the challenges to integrate guideline recommendations and heart failure knowledge into every-day life. Equally, clinicians saw value in a tailored care plan which involved the patient and family, particularly focusing on providing ongoing, evidence-based information and education.

The third design implication was to manage all stakeholders in heart failure care. The involvement of others in heart failure self-management was evidenced in all interviews, irrespective of the stakeholder group. For patients, the spouse and general practitioner were the main personal and professional stakeholders involved in heart failure self-management activities. Informal caregivers were heavily involved but this can be tiring for them as they balance caring duties with living their own life. Clinicians reported suboptimal follow up care and connected care, but stressed the importance of involving the specialist, multidisciplinary team members available on the St Vincent's Hospital Campus. Clinicians also highlighted the need to leverage existing written education material as expert opinion.

In addition to the research outputs, the research activities reported in this chapter uncovered insights into conducting multi-stakeholder co-design research. The variation in participation of stakeholders was evident early in Phase I. Recruitment and engagement varied greatly between stakeholder groups as clinicians were overwhelmingly positive about participating, whereas patient and family caregiver recruitment was sluggish. Contrary to expectations, participation did not appear to be age-specific for patients and family caregivers. Several potential participants in the 50-70 age group who were aware of the call for research participants chose not to self-select, reporting similar reasons to the 70+ age group. Reasons for non-participation included, but were not limited to: disinterest; medical concerns; exhaustion; shortness of breath; and non-ownership of a smart device. To increase participation, an additional recruitment site was added, the St Vincent's Clinic. Additionally, face-to-face visits and follow-up emails were sent to key clinicians in both recruitment

sites to ensure patients were aware of the call for research participants. Once 11 patients and family caregivers were recruited, recruitment was discontinued.

Conversely, clinicians were enthusiastic participants but nevertheless reported competing priorities with their clinical work. To ensure clinicians were able to attend the interview in respect of these competing priorities, flexibility of the day, time and location was offered. Further, clinicians were given the option to reply to the same questions via email correspondence (unlike patient and family caregivers where face-to-face interviews were necessary to uncover experience data). To minimise clinicians' time away from clinical care, interviews were kept as short as possible whilst ensuring Research Objective 1 was addressed. Refreshments were provided for clinicians who may have attended the interview during their work break. These strategies resulted in the efficient progression of the research activities and this was important as the preparations for the design workshops in Phase II were underway.

Chapter 5 : Phase II - Collaborative design and iterative development

Chapter 5 presents the findings from Phase II consisting of the ideate and prototype Design Thinking stages as per Figure 16.

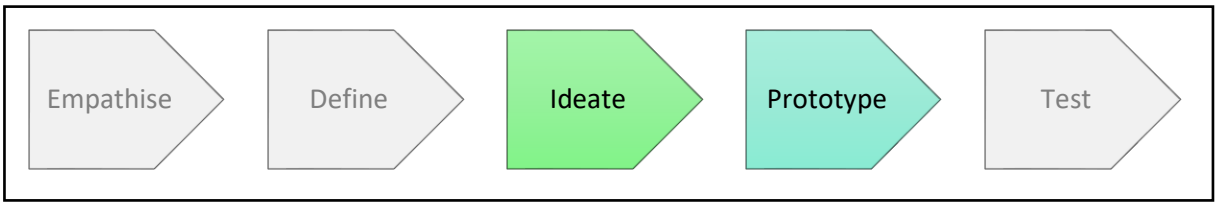

FIGURE 16. IDEATE AND PROTOTYPE STAGES OF THE DESIGN THINKING PROCESS

Ideation occurred in workshop activities conducted with all stakeholders and is where the mHealth app was conceptual designed. Prototyping activities involved the creation of a storyboard, wireframes and finally, a software version of the app. Prototyping activities occurred with individual participants. Chapter 5 addresses Research Objective 2: To collaboratively design and iteratively develop a mobile health app with patients, family caregivers and clinicians.

An important change in terminology occurs between Chapter 4 and Chapter 5. From Chapter 5 onwards, the visual representations of experience data referred to in Phase I will now be termed ‘design artefacts’. Design artefacts are material objects that can be viewed by others, used to challenge perceptions and inspire new ideas (Lupton, 2018). The rationale for delaying the use of the term is explained in the terminology section (section 1.6).

Design artefacts used in workshop activities in Phase II (reported in this chapter) were adapted from Phase I outputs. Figure 17 presents the design artefacts used in the study procedures for Phase II including the stakeholder map, journey map, current care summary, design brief and personas. As per Figure 15 (section 4.5) design artefacts in green represent data from the patient and family caregiver stakeholder group, blue represents that of the clinician stakeholder group and yellow (the design brief) represents a composite of both stakeholder groups.

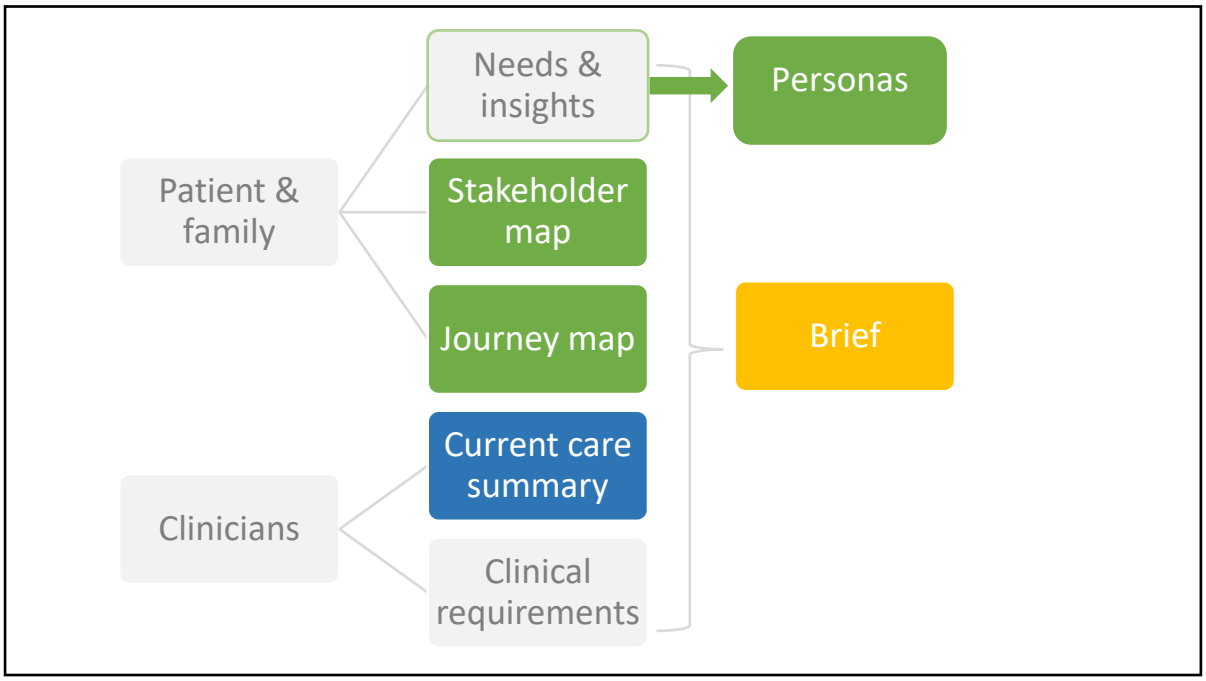

FIGURE 17. DESIGN ARTEFACTS USED IN PHASE II

Chapter 5 is divided into the following sections:

Section 5.1 provides the preface to Publication 5 which details the process for the development and use of personas as a user-centred design technique;

Section 5.2 presents Publication 5 - *The development and use of personas in a user-centred mHealth design project* published with the Association for Computing Machinery in 2017. The publication provides an explanation of how personas were developed from the needs and insights summary as reflected in Figure 17;

Section 5.3 is the preface to Publication 6, which presents the design and development processes undertaken to achieve the software version of the app. Conceptual design activities took place in co-design workshops and iterative development processes involved feedback and improvement cycles with app wireframes;

Section 5.4 presents Publication 6 - *Conceptual Design and Iterative Development of a mHealth App by Clinicians, Patients and Their Families* published in Studies in Health Technology and Informatics in 2018; and

Section 5.5 provides a summation on Chapter 5 explaining how it addresses Research Objective 2. The research output, the *Care4myHeart* app, is described as ready for deployment in a usability study to be conducted in Phase III.

5.1 Preface to Publication 5

Publication 5 presents one component of the ideation stage, patient personas. Personas are fictional characters based on research data used in design to help understand different perspectives and situations (Nielsen, 2011). Personas were a key design artefact that were developed by analysis of the needs and insights summary findings from Phase I. Personas were used to facilitate ideation in design workshops in Phase II. The aim of Publication 5 was to present a summary of the development and use of personas in this context.

The *Association for Computing Machinery* (ACM) published Publication 5 in the proceedings of the 29th Australian Conference on Human Computer Interaction (OzCHI '17). The paper was presented orally at the conference held in Brisbane, Australia in November 28 -December 1, 2017. The research presented in Publication 5 contributes to the knowledge-base in two ways. Primarily, the publication offers a process for clinicians to consider for intervention design as a way to capture and represent the patient experience. Additionally, the personas themselves could be used by other heart failure research teams in practical design activities.

The citation for Publication 5 is:

> L. Woods, J. Duff, E. Cummings and K. Walker. 2017. The development and use of personas in a user-centred mHealth design project. In *Proceedings of the 29th Australian Conference on Human Computer Interaction (OzCHI '17)*, Nov 28- Dec 1, Brisbane, QLD, Australia, Alessandro Soro, Dhaval Vyas, Bernd Ploderer, Ann Morrison, Jenny Waycott, and Margot Brereton (Eds.). ACM, New York, NY, USA, 560-565. The publication is available at the ACM Digital Library through https://doi.org/10.1145/3152771.3156186

Approval to use figure 5 (photo of workshop participant conducting an activity) was granted by the workshop participant. The four persona images were extracted from Pexels.com with a creative Commons Licence: no permission or acknowledgement was required for these images.

5.2 Publication 5: The development and use of personas in a user-centred mHealth design project.

See next page.

The development and use of personas in a user-centred mHealth design project

Leanna Woods
St Vincent's Private Hospital
Sydney Darlinghurst, NSW,
Australia
Leanna.Woods@svha.org.au

Jed Duff
School of Nursing and Midwifery
University of Newcastle, NSW,
Australia Jed.Duff@newcastle.edu.au

Elizabeth Cummings
School of Health Sciences
University of Tasmania, TAS,
Australia
elizabeth.cummings@utas.edu.au

Kim Walker
St Vincent's Private Hospital
Sydney Darlinghurst, NSW,
Australia Kim.Walker@svha.org.au

ABSTRACT

Heart failure self-management can be complex and challenging. We are collaborating with healthcare professionals, patients and families to co-design a consumer mHealth application in support of heart failure self-management. Four patient-modelled personas, developed through ethnographic interviews, were used in co-design workshop activities to represent the patient experience and associated health challenges. We explain how persona use benefited patients, the design team and the project lead in terms of efficiency, effectiveness and anonymity, in our commitment to developing a mHealth application which meets the needs of our patients and is clinically relevant.

OzCHI '17, November 28-December 1, 2017, Brisbane, QLD, Australia
 ACM ISBN 978-1-4503-5379-3/17/11.
https://doi.org/10.1145/3152771.3156186

CCS CONCEPTS

•**Human-centered computing~User models** • *Human-centered computing~User centered design* • *Human-centered computing~Participatory design*

KEYWORDS

mHealth; persona; user-centred design; hospital; healthcare

ACM Reference format:

L. Woods, J. Duff, E. Cummings and K. Walker. 2017. The Development and Use of Personas in a User-Centred mHealth Design Project. In *Proceedings of the 29th Australian Conference on Human-Computer Interaction, Brisbane, QLD, Australia, November 2017 (OzCHI 2017)*, 4 pages.
https://doi.org/10.1145/3152771.3156186

1 INTRODUCTION

Heart failure - a highly symptomatic syndrome of impaired heart function - is a major public health issue in Australia [4]. As with other chronic diseases the expense of heart failure on the healthcare system is significant, costing in excess of one billion Australian dollars annually [4]. Tailored, patient-centred innovations are necessary to support home-based self-management for the improvement in quality of life and to decrease costly re-hospitalisations. At the St Vincent's Hospital Campus Sydney, we provide specialised, evidence-based, multidisciplinary heart failure care, education and treatment planning. We disseminate written literature authored by the National Heart Foundation of Australia [5] offering simplified guidelines together with strategies to encourage daily self-monitoring, appropriate care-seeking and concordance to treatment plans. Current challenges include maintaining access of services to all patients in our community, avoiding preventable re-hospitalisations and the provision of regular, ongoing personalised care based on the context-specific needs of our patients. At a time when digital innovation is experiencing exponential growth, currently there are no appropriate mHealth applications recommended for safe use by our patients to assist with heart failure self-management.

2 AIM

Using participatory user-centred design principles, we aim to co-design a consumer mHealth application to support patients with heart failure to self-manage their condition. This paper reports the development and use of patient-modelled personas in the co-design process.

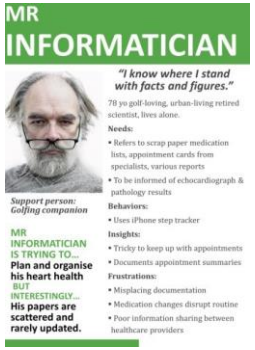

Figure 1: Persona: Mr Informatician. Image courtesy of Pexel.com

Figure 2: Persona: Mrs Distracted. Image courtesy of Pexel.com

3 PROJECT

To meet the challenges and complexity experienced by patients, we will develop a novel mHealth solution to support heart failure self-management, which we plan to implement to positively impact patient outcomes. Lead by a local Cardiac Clinical Nurse Specialist (first author), mHealth application development will continue throughout 2017 with the aim of conducting usability testing in 2018. For the collaborative design project, seven patients and four family members were recruited alongside seven multidisciplinary healthcare professionals (nursing, medical, pharmacy, physiotherapy and dietetics) from the St Vincent's Hospitals Campus, Sydney.

The first step involved ethnographic interviews with patients and family members to gather a deep understanding of their experience of heart failure self-management. Secondly, all stakeholders were invited to attend two 2-hour collaborative design workshops conducted on the hospital campus to define the features and functions of the mHealth application. Currently, we are developing a low-fidelity digital prototype to conduct design iterations with the dual aim of meeting the needs of patients and ensuring clinical relevance. Once the design team reach consensus regarding the quality of the digital prototype, software development will occur.

Personas were considered for use in this project to support a patient-centred design. Personas are fictional characters based on data, who represent potential users [6]. In this case, 'users' are patients with heart failure who would use a mHealth application for heart failure self-management. As advocated by Nielsen [6], we used personas to allow the everyday experiences and inherent needs of patients be the departure point of designing our innovation.

3.1 Persona Development

Ethnographic interviews conducted with 11 self-selecting patients and family members allowed for a deep understanding of their daily life with heart failure. Lasting around an hour, interviews were conducted on the hospital campus in the patient's room, ward common room or hospital cafeteria. An informal, non-audiotaped approach built rapport, aided open dialogue and facilitated detailed storytelling. The empathic approach allowed us 'to see the world through the eyes of others, understand the world through their experiences, and feel the world through their emotions' [1]. In order to elicit insights from experiences and emotions, participants were asked open-ended questions such as *'What's your experience of managing your health at home?'*, *'How do you go with it?'* and *'What is your favourite and least favourite part?'* Detailed notes including verbatim quotes were taken during the interview. To capture subjective and objective qualitative data an 'Empathy Map' was completed immediately following each interview [2];

- Said; What are some quotes and defining words the user said?
- Think; What might the user be thinking? What does this tell you about his/her beliefs?
- Do; What actions and behaviours do you notice?
- Feel; What emotions might the user be feeling?

Figure 3: Persona: Mr Deflector. Image courtesy of Pexel.com

Figure 4: Persona: Ms Content. Image courtesy of Pexel.com

Empathy map content was thematically analysed using colour coding of salient themes. For example, content relating to health information management including the associated emotional responses to managing health information, became the basis of the first persona named *Mr Informatician* [figure 1]. Content relating to the challenge and complexity of symptom management resulted in the formation of *Mrs Distracted* [figure 2], and so on [figure 3; figure 4]. Similar themes were merged resulting in the formation of four final, believable character profiles. Fictional socio-demographic information was added to make the personas realistic and relatable, whilst maintaining anonymity to the interviewed participants. We developed posters containing the personas to represent the needs, insights, behaviours and frustrations of potential end-users of our novel mHealth application.

2. Persona Use

Personas were used in two design workshop activities conducted on the hospital campus in our commitment to designing a patient-centred application. Large posters were displayed on walls and team members were given an A4-size copy containing the personas for reference and annotations. Additionally, a poster outlining the design criteria identified the three broad guidelines produced from the needs of patients and requirements by healthcare professionals, to be addressed in the design. First, design team members were asked to generate a multitude of possible solutions using an 'Idea Matrix' and then were asked to draw a 'Solution Sketch' to bring abstract ideas into a definite visual solution. These activities were the basis to produce a storyboard of the novel mHealth application by the completion of the second workshop.

1. *Idea Matrix.* Using multiple post-it notes on a large whiteboard divided in a grid of four columns (representing each persona) and three rows (representing each design criteria) we generated a multitude of ideas. Design team members were asked to ideate solutions to each design criteria based on each persona's needs; see [figure 5]. For example, in the box representing possible solutions to support Mr Informatician to address medication and symptom management challenges (design criteria 1), a post-it note idea read 'an interactive medication list with reminder function'. After 30-minutes, dozens of ideas were generated, after which whiteboard grid lines were removed allowing design team members to physically cluster post-it ideas next to other similar ideas. Collectively naming each cluster sparked group discussion and provided a summary of the preferred design solution features for the next activity.
2. *Solution Sketch.* Adapted from a design sprint activity [3], design team members sketched a solution to a heart failure self-management challenge from one persona of their choosing. Predominantly, healthcare professionals chose a challenge related to their specialist area of experience and the patient representative chose a relatable challenge to his own experience. This incorporated the strengths, perspectives and expertise of each team member participating in the workshop. Imagining themselves in the chosen persona's situation, team members sketched a solution to the self-management challenge starting with drawing what the persona would expect to see on the home screen of the mHealth application, to the series of steps to achieve a desired outcome. Sketches were shared, solutions critiqued and a visual vote of coloured stickers enabled efficient collaborative decision-making prior to the final activity; storyboarding the application interface.

Figure 5: A design team member participating in the 'Idea Matrix' workshop activity.

4 DISCUSSION

The use of personas had benefits for patients, design team members and the project lead. Ethnographic interviews were used to empathise with patients who live with heart failure in the home setting. Personas were a design tool used by the project lead to communicate these findings to the design team. They enabled progression of the project without the responsibility of patients taking on this role themselves and in the absence of end-users in the workshops. The majority of our participant volunteers declined our invitation to attend the design workshops but consented to ethnographic interviews and prototype feedback. Personas had the advantage of allowing patients to be involved in the innovation and their needs represented without attention on them directly [6]. The design team benefited from exposure to the 'user voice' provided by the persona types throughout the development process. Importantly, personas allowed design team members to discuss from the same understanding of context and needs [6] lessening individual's unconscious biases. Empathic decision-making of features and functions of the mHealth application was facilitated by regular familiarisation of the persona types during workshop activities. Design work and certainly persona use, was not familiar to our team of healthcare professionals, providing a creative, novel and playful process different from their usual work activities.

Organisation wide, it was necessary to use strategic, efficient processes to limit team member's time away from their professional healthcare responsibilities to participate in this development. Using personas in a collaborative setting, we progressed the project rapidly and were able to storyboard a mHealth application for heart failure self-management in two 2-hour design workshops, ready for transfer into a low-fidelity digital prototype.

5 CONCLUSIONS

When designing consumer mHealth applications, understanding the patient experience is crucial to ensure the design meets the needs and requirements of the target end-users. Interviews translated dialogue and observations into insights which was represented in the design phase through the use of personas. As a functional design tool in collaborative healthcare workshops, personas provide an opportunity to empathise with patients by viewing health challenges objectively and visually. Persona use helped with managing the complexity of the project through limiting human resource use of volunteer participants and healthcare professionals. We leveraged the skills and experience of local staff and patients and used existing hospital resources within our familiar healthcare environment in the pursuit of a respectful, efficient co-creation process for all stakeholders.

ACKNOWLEDGMENTS

This project is supported by a St Vincent's Clinic Foundation Grant and the University of Tasmania's Elite Research Scholarship funded by The District Nurses. No conflicts of interest.

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5.3 Preface to Publication 6

Publication 6 presents a summary of the conceptual design activities and iterative development processes conducted with co-design participants. Conceptual design activities took place in two design workshops conducted on the hospital campus using structured design activities including group work, discussion and individual brainstorming. Iterative development processes entailed the production and refinement of wireframes as clickable prototypes of the novel mHealth app. Software development processes are also summarised. The output of each step was the input to the next step.

The objective of Publication 6 was to describe the systematic processes co-design participants undertook to design and develop the mHealth app, especially as hospital staff and consumers without previous design experience. The discussion focuses on the strengths of the participatory approach to the in-hospital design and development, specifically as it related to leveraging the expertise and perspectives of a variety of stakeholders whilst respecting their time as volunteer participants.

Studies in Health Technology and Informatics was the Series for Publication 6. The publication was associated with an oral presentation in the 26th Australian National Health Informatics Conference (HIC 2018) which occurred in Sydney, Australia during July 30 - August 1, 2018. It was published online via open access through IOS Press in the series titled *Connecting the system to enhance the practitioner and consumer experience in healthcare*. The greatest contribution of this publication to the knowledge-base is explaining a pathway for clinician-led mHealth co-design within a health service. Publication 6 was shortlisted for the Branko Cesnik Best Student Paper Award finals.

The citation for Publication 6 is as follows:

> Reprinted from Studies in Health Technology and Informatics, vol. 252, Woods, L., Cummings, E., Duff, J., & Walker, K., Conceptual Design and Iterative Development of a mHealth App by Clinicians, Patients and Their Families, pp. 170-175, Copyright (2018), with permission from iOS Press. The publication is available at IOS Press through http://dx.doi.org/10.3233/978-1-61499-890-7-170

5.4 Publication 6: Conceptual Design and Iterative Development of a mHealth App by Clinicians, Patients and Their Families

See next page.

Connecting the System to Enhance the Practitioner and Consumer Experience in Healthcare
E. Cummings et al. (Eds.)

doi:10.3233/978-1-61499-890-7-170

Conceptual Design and Iterative Development of a mHealth App by Clinicians, Patients and Their Families

Leanna WOODS[a,b,1], Elizabeth CUMMINGS[a], Jed DUFF[c] and Kim WALKER[b]
[a] *School of Health Sciences, University of Tasmania, Australia*
[b] *St Vincent's Private Hospital Sydney, Australia*
[c] *School of Nursing and Midwifery, University of Newcastle, Australia*

Abstract. Heart failure self-management can be challenging but appropriately designed, user-centred mobile health (mHealth) innovations may help. We have built a consumer mHealth application which we plan to implement as an adjunct to existing specialist multidisciplinary heart failure care at our health service. We have the double aim to meet the needs of patients and ensure clinical relevance in order to be recommended by clinicians. This paper reports the participatory, user-centred co-design process of the conceptual design and iterative development of the application. Two nurse-led participatory design workshops were conducted with six clinicians and a patient, which determined user-experience opinions, key features and priority functions. The iterative development phase encompassed two application wireframe feedback cycles with seven clinicians, three patients and a family member. Workshops and wireframe feedback activities took place on the hospital campus predominantly using resources available to clinicians. Software build was outsourced and was followed by the design team reaching consensus with features and functions of the app. Further development and evaluation of flexible participatory, user-centred methods for use by clinicians to facilitate co-design with consumers will advance consumer digital health strategies.

Keywords. mHealth; participatory design; co-design; consumer application; user-centred design

Introduction

Leveraging the advancement of technologies, novel ways to provide patient-centred healthcare have emerged to address the burden of chronic conditions and the financial sustainability of health services. Currently in our health service, no consumer mobile health (mHealth) application (app) is recommended for safe use in the self-management of heart failure. This chronic, highly symptomatic syndrome of the heart muscle requires symptom self-monitoring, lifestyle changes and concordance to treatment pathways; alongside support from a multidisciplinary team of healthcare professionals [1]. The experience of self-management in this patient population is reported as being complex, challenging and tiring [2].

This research involves the in-hospital development of a novel mHealth application which could be implemented as an adjunct to existing care for optimised patient

[1]Corresponding Author: Leanna Woods; Email: leannaj@utas.edu.au.

empowerment and wellbeing. It is based on the premise that validated consumer apps should have the potential to improve consumers' self-management [3]. Our methodology focusses on the double aim to meet user requirements and ensure relevance to local clinincians. Prior work conducted by this research team [4] discovered patients and providers could benefit from a solution that addresses medication and symptom management challenges, involves a self-care plan and manages all stakeholders in care effectively. The brief was to design a consumer application to support people with heart failure to live well at home.

This paper reports the processes, personnel and resources involved in the nurse-led conceptual design and iterative development of the patient-facing mHealth application by clinicians, patients and their families.

1. Process

The design and development processes followed a deep understanding of the patient and family experience and a needs assessment conducted with clinicians. Conceptual design activities occurred during two participatory design workshops where user-experience opinions, key features and priority functions were determined. Iterative development commenced with the creation of wireframes - a visual, interactive representation of app screens on a laptop computer. Feedback and improvement cycles with individual co-design team members were conducted until there was consensus that the features and functions of the application were accurately represented. The final development phase describes the improvements following the application build by the software partner. The workshops and subsequent app development activities were lead by a registered nurse (lead author) who had extensive clinical experience but limited design experience. The output from each activity was the input into the next activity; see figure 1. Detail of the conceptual design and the iterative development processes are described in the following sections.

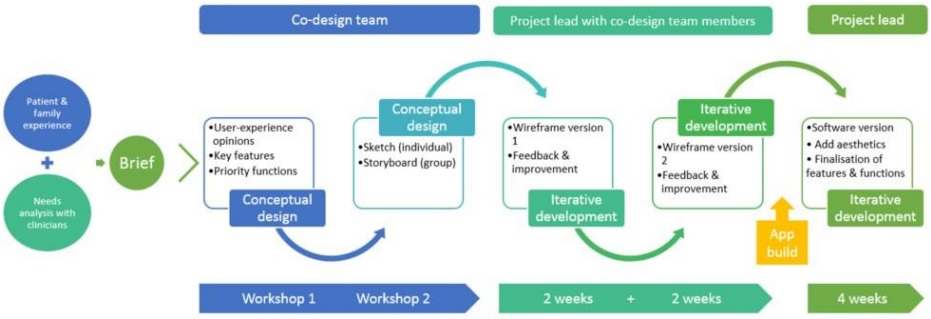

Figure 1. Design and development process, personnel and timeline.

1.1. Conceptual Design

Seven volunteer co-design team members (six clinicians and one patient) were recruited from our health service to attend two 2-hour participatory design workshops conducted on the hospital campus. Clinicians represented nursing, pharmacy, physiotherapy and dietetics backgrounds.

1.1.1. Workshop 1

In the *Lightning Demos* activity [5] individuals reviewed personal smartphone applications they considered enjoyable, useful and user-friendly. Working in two groups, team members were asked to decide on a summary of favourable app features and functions. Secondly, team members were encouraged to brainstorm multiple, varied potential solutions to health challenges associated with four previously-developed personas [4]. Solutions considered by the group for possible inclusion in the app were clustered among similar solutions and the cluster was given a label. Based on field notes, photographs and individual summaries, data was further summarised by the project-lead at the completion of the first workshop. This resulted in three groups of concepts; user-experience opinions, key features and priority functions. Three posters (labelled A, B and C) containing these findings were developed using the accessible language statements; *we'd like the app to be…*, *we'd like the app to contain* and *our ideas so far are…* See table 1.

Table 1. Representing the initial design concepts generated in workshop 1.

Poster	Group of concepts	Accessible language
A	User-experience opinions	We'd like the app to be…
B	Key features	We'd like the app to contain…
C	Priority functions	Our ideas so far are…

Detail specific to our healthcare context and therefore relevant to our patient population was represented by infographics within each poster in preparation for the next workshop.

1.1.2. Workshop 2

In the second workshop co-design team members reviewed and discussed the poster content, adding three more design concepts. The aim of the second workshop was to progress the initial design concepts to a refined design from which wireframes could be built. Using pens and paper, co-design team members individually produced a *Solution Sketch* [5] representing how a user would interact with the mHealth application. Sketches were shared and through a facilitated group discussion, favourable components were shortlisted. In the final activity, a comic-like *Storyboard* [5] of the main features and functions of the application was collaboratively created on a whiteboard. The team attached six individual paper sketches, 12 'main feature' comments and 10 'design consideration' comments to their work. The storyboard was developed in 45 minutes using a variety of materials such as markers, paper, different coloured post-it notes and voting stickers. A total of 14 frames of sketches, labels and descriptions were developed accurately representing the team members' priorities for user interaction with the mHealth application to address perceived self-management challenges. Frame content and sequence was considered as input to the first cycle of development.

1.2. Iterative Development

Two patients, a family member and a another clinician joined the team to participate in the development (totalling 11 team members including seven clinicians, three patients and one family member). Two wireframe versions were produced during a series of iterative development activities which resulted in a defined, clickable representation of

the app with enough detail for the initial software build. This was then revised to produce a final product.

1.2.1. Wireframe Versions

Wireframes were produced by the project lead within Microsoft® PowerPoint using the low-cost PowerMockup software add-on (Wolfsoft, Germany, ©2018). This software provided generic app templates, icons and directional options and was easily navigated by the project-lead who has no experience in computer programming. Each wireframe screen, as well as the functionality provided between screens through clickable hyperlinks, demonstrated the user-experience for review by the team. Individual team members assessed the summarisation by the project lead was accurate. To do this and for design improvement, feedback data containing what worked, what could be improved, questions to be answered and further ideas, was collected using a feedback template; see figure 2.

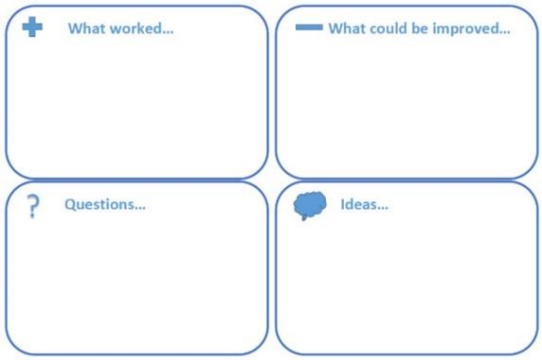

Figure 2. Wireframe feedback template.

Where possible each team member's feedback was incorporated prior to the next feedback session resulting in five updates of each version. Seventy-five wireframes were produced by the completion of version 1 which increased to 89 in version 2 due to user-interface specification. The nurse-led feedback process occurred on the hospital campus either in the cafeteria or clinicians' office, each session lasting 50-60 minutes. Due to geographic and time restrictions some team members provided feedback via email or phone by viewing the wireframes electronically. The approximate length of time it took the project-lead to update each version was 48 and 32 hours respectively.

1.2.2. Software Version

The application was built in January 2018, ready for debugging and prototype finalisation. The project-lead worked closely with the software development partner using a freely-available online collaborative project management website Trello.com (Trello®, Atlassian, ©2018). Importantly, the software version needed to accurately represent the information and functionality decided by the co-design team in the final wireframe version. Additional aesthetic elements such as the colour palette, logo graphic and icon design were confirmed, adding to the quality of the app. To achieve a stable product for use, this process took nine software builds (Android and iOS), multiple

bidirectional communication threads and in excess of 80 hours of time for the project-lead.

2. Discussion

In the design and development process, we report the workshop, wireframe and software development activities conducted by our team. Patients, family members and clinicians were included in our pursuit of a well-designed product which would be supported, in principle, by the multidisciplinary healthcare professionals providing care to this patient group. Ongoing and regular engagement with multiple stakeholders had many benefits. Firstly, use of participatory, user-centred procedures leveraged the different strengths and perspectives in an active and continuing negotiation between the needs of both stakeholders. Recommendations from research findings and theoretical perspectives reported in a recent scoping review [6] support a user-centred, interdisciplinary and collaborative approach to mHealth design to enhance feasibility, acceptability and usability.

Secondly, providing a variety of environments and materials supported inclusion of team members regardless of personality type, technology familiarisation and scheduling availability. For example, volunteer team members who participated in group activities within workshops were introduced to health technology design and were facilitated through collaborative brainstorming and decision-making activities while defining tangible solutions. For those preferring individual interactions, and to refine the wireframes, individual feedback sessions with the project-lead ensured diverse perspectives and preferences were accurately represented as the research progressed.

Finally, we benefited from having a project-lead who is a clinician familiar with the healthcare context and was involved in each research phase. During the software feedback cycle conducted independently with the software developer, the project-lead acted as an advocate for patients, family members and clinicians involved in the previous phases to ensure that the user- and clinician- requirements were addressed as the application was built.

Digital health designers need to document case studies and experiences to advance the knowledge base for in-hospital co-design of mHealth solutions. In our example, the participatory co-design practices conducted by a clinician aimed to limit the burden on the volunteer team members but capitalise on their skills and perspectives. The process was engaging and dynamic yet complex in recognition of designing a new innovation which needs to acknowledge the current reality of health service delivery, variations in patient experience and limited awareness of the possibilities of technology. Being located within a single health service allowed us to engage with our community of patients and providers as we hope to produce a useful product fit-for-purpose to current clinical practice. Well-defined, efficient co-design processes which take place within a health service add value to patient-centred healthcare delivery and needs further investigation.

The authors acknowledge the absence of user-experience experts as a limitation of this study and we plan to engage with these experts as we refine, test and plan for its implementation. The possibility of replicating these development processes through patient-facing mHealth technologies for other chronic conditions requiring self-management could be assessed for suitability.

3. Conclusion

We report the conceptual design and iterative development processes of a consumer mHealth application conducted on our hospital campus by clinicians, patients and family members. The context-specific app will complement our service by adding a new heart failure self-management tool for optional use by local patients.

Using participatory design processes to develop our mHealth application allowed for the inclusion of diverse perspectives from different stakeholders into the product's features and functions. Whilst end-users of consumer applications are patients themselves, healthcare teams need to lead design and development procedures in order to endorse such digital health technologies alongside current healthcare delivery. Accurate, evidence-based and validated mHealth apps, if designed with a balance of consumer and provider input, can be safely used where most of the care for people living with chronic conditions takes place; the home. A variety of flexible and inclusive participatory, user-centred methods should be used and evaluated by clinicians when designing with consumers to ensure the quality and suitability of consumer health technologies.

Acknowledgements

We are grateful to the patients, family members and clinicians who contributed with their valuable ideas and suggestions. We would like to thank Andreas Wulf from Wulfsoft for providing a free license of PowerMockup. This project is supported by a St Vincent's Clinic Foundation Grant and the University of Tasmania's Elite Research Scholarship funded by The District Nurses. No conflicts of interest.

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5.5 Chapter 5 summation

The output of the research reported in Chapter 5 was the final design of the mHealth app, named *Care4myHeart*. *Care4myHeart* is a consumer self-management support app created by a multi-stakeholder team of patients, family caregivers and clinicians. Chapter 5 presented the ideation and prototype Design Thinking stages also known as Phase II of the research. The conceptual design of the app which included the use of personas to represent the needs and insights of patients was reported. Then the iterative development processes used for wireframe and software build were reported. Chapter 5 contributed to addressing Research Objective 2: To collaboratively design and iteratively develop a mobile health app with patients, family caregivers and clinicians.

The active involvement of stakeholders was the strength of the research procedures reported in this chapter. Stakeholder participation ensured the efficient progression from concept to development to build. However, careful negotiation between stakeholders was required as the development progressed. Noted to be challenging to manage in health projects (Skeels & Pratt, 2008), we highlight a few examples how tensions between stakeholders were negotiated.

The first example is the late inclusion of the wellbeing sub-section. Psychological considerations were not identified during initial workshop activities, yet a patient highlighted the need for the wellbeing component to be added to the design in the second workshop. Clinicians responded immediately, agreeing with the need to include the psychological and wellbeing elements into the app. Clinicians stated they missed this concept because they 'provide psychological support in every patient interaction' without it being a tangible item in conceptualising the app's design. Addressing other stakeholders directly in a co-design process has been proposed as being beneficial for mutual learning (Skeels & Pratt, 2008). In our case the wellbeing sub-section represents a design which merged provider and consumer perspectives achieved through facilitated multi-stakeholder discussion.

The second example occurred in the iterative development phase. The location of the icon labels representing the sub-sections constantly changed as team members preferences varied considerably. The design evolved over time with the resultant app representing where the user would expect the icon labels to be rather than where the clinicians thought they should be. Navigating opposing opinions was facilitated via guided discussions with co-design participants about the design goals and reiteration that co-design was an opportunity to displace existing heart failure interventions. In this process, power was given to patients to decide on the user experience focusing on what the user would 'expect' to see on a certain page, rather than the existing, rigid,

clinical format of care guides familiar to clinicians. It was important that the heart failure care guides were not simply replicated in a digital format. The co-design process was an opportunity for a user-centred philosophy and build a new design rather than replicate an existing design.

Use of personas provided depth to the complex health challenge that the stakeholders were designing for. Although it may have been acceptable to conduct the workshops without the personas, persona use was associated with specific advantages. Primarily, personas were a creative, visual format in which the needs and insights gathered from patients themselves were represented without their attendance in co-design activities. Secondly, personas presented an opportunity to list the multiple, complex healthcare challenges of a nonhomogeneous patient sample to benefit structured activities in order to develop a solution which may address these challenges.

Clinicians interested in designing interventions to improve the patient experience may consider using multi-stakeholder workshops to ideate solutions. The clickable prototype represented a mHealth solution to address the healthcare challenge of improving heart failure self-management (the research question). A mHealth app was the design goal as per the design brief, and consistent with the research aim. However, the solution may not have been a mHealth solution and it is important to note that workshop activities presented in this chapter could have yielded an alternative prototype.

In Chapter 5 the conceptual design and iterative development of the app was presented. The developed app, *Care4myHeart*, is a functional mHealth intervention for Android and iOS which was able to be deployed for usability testing on a new subset of patients with heart failure. Next in Chapter 6, the user interface of the developed app is presented and the findings from the usability study are explained.

Chapter 6 : Phase III - Usability test with patients

Chapter 6 reports the research conducted in Phase III to address Research Objective 3: To understand the patient experience using the app for heart failure self-management. The first section of the chapter explains the features and functions of the final software version used for testing, followed by the findings from the usability study conducted with a new subset of patients with heart failure.

First, Publication 7 presents the final design of the app in the context of the rationale behind the design in the preceding phases. Describing the final design encompasses the features and functions of the app interface and represents the findings from the co-design team in terms of their perspectives and opinions on an intervention to support heart failure self-management. The final software version was used by patients in the usability study. Consequently, Publication 8 reports the 'test' Design Thinking stage, where potential end-users test the app for usability and suitability for heart failure self-management. Figure 18 represents the test stage of the Design Thinking process.

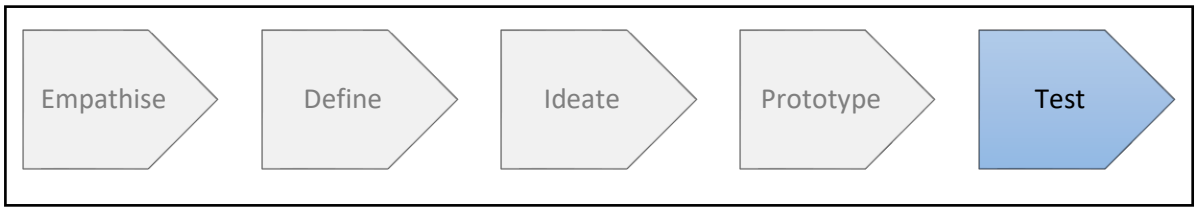

FIGURE 18. TEST STAGE OF THE DESIGN THINKING PROCESS

Chapter 6 is divided into the following sections:

Section 6.1 is the preface to Publication 7 which presents the final software design of the app interface in the context of the findings of the rigour and relevance activities conducted throughout the development. The final design of the app represents the consensus of co-design participants as to the features and functions;

Section 6.2 presents Publication 7 - *Design of a Consumer Mobile Health App for Heart Failure: Findings from the Nurse-Led Co-Design of Care4myHeart* submitted to the Journal of Medical Internet Research (JMIR) Nursing;

Section 6.3 provides the preface to Publication 8 which reports the qualitative and quantitative findings of a 14-day usability study conducted to understand the experiences of patients using the app for heart failure self-management;

Section 6.4 presents Publication 8 - *Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study* published with JMIR Human Factors in 2019; and

Section 6.5 provides a summation on Chapter 6 and how it addresses Research Objective 3.

6.1 Preface to Publication 7

The final design of *Care4myHeart* is presented in Publication 7. The format of the manuscript presents an overview of the co-design process, explanation of the app components and a justification of the app components based on the findings elicited from the co-design process. Consistent with the Design Science Research Cycle framework (explained in section 3.3.1), the relevance information (stakeholder experience data) and rigour information (evidence-based literature) is listed as the rationale for the final design features. The discussion focuses on the strengths and limitations of incorporating stakeholder experience data and the evidence-based literature, on the final design.

Reporting the app components on the user interface was necessary before reporting the usability study conducted with a new subset of patients. The usability study is reported later in the chapter in Publication 8 (section 6.4).

Journal of Medical Internet Research (JMIR) Nursing was the chosen journal for Publication 7 to be submitted to. *JMIR Nursing* is a new sister journal to JMIR, the leading eHealth publisher. It is an international, peer-reviewed and open access journal with a core purpose to bring together academics and practitioners to advance improvements in health and care service provision. As a nurse conducting digital health research, submission to *JMIR Nursing* positions the work to the readership of the local network of health informaticians. The publication contributes to the body of knowledge on the features and functions of a consumer mHealth app for heart failure, as elicited through a co-design process involving many stakeholders.

The details of the submitted manuscript representing Publication 7, is as follows:

> Woods, L., Duff, J., Roehrer, E., Walker, K., & Cummings, E. Design of a Consumer Mobile Health App for Heart Failure: Findings from the Nurse-Led Co-Design of *Care4myHeart*. (Submitted manuscript, JMIR Nursing)

6.2 Publication 7: Design of a Consumer Mobile Health App for Heart Failure: Findings from the Nurse-Led Co-Design of *Care4myHeart*

Abstract

Background: Consumer healthcare technology shows potential to improve outcomes for community-dwelling persons with chronic conditions, yet health application (app) quality varies considerably. In partnership with patients and family caregivers, hospital clinicians developed *Care4myHeart*, a mobile health app for heart failure (HF) self-management.

Objective: The aim of this paper is to report the outcomes of the nurse-led design process in the form of the features and functions of the developed app, *Care4myHeart*.

Methods: Seven patients, four family caregivers and seven multidisciplinary hospital clinicians collaborated in a Design Thinking process of innovation. The co-design process, involving interviews, design workshops and prototype feedback sessions, incorporated the lived experience of stakeholders and evidence-based literature in a design which would be relevant and developed with rigour.

Results: The *home screen* displays the priority HF self-management components with a reminder summary, general information on the condition and a settings tab. The *health management* section allows patients to list healthcare team member's contact details, schedule medical appointments and store documents. The *My Plan* section contains nine important self-management components with a combination of information and advice pages, graphical representation of patient data, feedback and more. The greatest strength of the co-design process to achieve the design outcomes was the involvement of local patients, family caregivers and clinicians. Additionally, incorporating the literature, guidelines and current practices into the design strengthened the relevance of the app to the healthcare context. However, the strength of context-specificity is also a limitation to portability, and the final design is limited to the stakeholders involved in its development.

Conclusion: We recommend health app development teams strategically incorporate relevant stakeholders and literature to design mobile health solutions which are rigorously designed from a solid evidence-base, and relevant to those who will use or recommend their use.

Keywords

Heart failure; mobile health (mHealth); mobile apps; self-management; mobile phone; co-design; user centred design

Introduction

The management of chronic conditions is an important public health challenge [1]. Globally, 26 million people live with heart failure (HF) [2], a chronic condition with considerable economic burden [3] which places great stress on patients, caregivers and healthcare services [2]. Supporting patients and caregivers in long-term HF care is essential [2] with self-management linked to better quality of life, lower mortality and readmission rates [4]. For these reasons, self-management is supported by healthcare policy [5, 6] and is the mainstay for disease management in HF [4, 7]. However, as with many chronic conditions, patients with HF find it difficult to follow self-care advice because it can be complex and challenging to sustain behaviour change over the long-term [4].

In an era of rapid technological advancement, there is growing interest in consumer digital health to help with improving health. Of the 318,000 plus mobile health (mHealth) applications (apps) available to consumers across the world [8], an abundance of health apps are available for self-monitoring [5] with condition-management apps now accounting for 40% of apps [8]. The widespread interest among patients with chronic conditions to use health technologies stretches across health status, age and other sociodemographic variables [9]. The quantity and variety of mHealth apps available presents an overwhelming choice for consumers [8, 10], often without guidance from their healthcare provider [10].

From the health provider perspective, the lack of evidence regarding the effectiveness of mHealth apps to improve healthcare outcomes limit their addition to treatment protocols [10]. Particular concerns are around the evidence of consumer apps regarding accuracy, efficacy and security [10], and the inconsistent impact on disease control and healthcare utilisation [11]. Most apps are developed outside health care systems [10], the average app quality is often low [8] and some may even threaten patient safety and privacy [12]. mHealth apps are not yet established for widespread and sustained use nor embedded in Australian health policy [5]. More locally, our health service's HF team does not currently recommend a HF self-management app to patients. However, the body of evidence regarding the health impacts of mHealth apps is expanding [5, 8], exampled by the growing number of clinical trials in recent years [10] and the value of mHealth to improve healthcare delivery is high among providers [10].

If we are to embrace consumer digital healthcare for its potential to address the burden of chronic conditions, interventions need to be well designed, evidence-based and fit-for-purpose for healthcare providers and healthcare consumers alike. With this in mind, the aim of this research was to use co-design processes to develop a consumer mHealth intervention for heart failure self-management that is both relevant to stakeholders and developed with rigour. This paper reports the outcomes of the nurse-led design process in the form of the features and functions of the developed app, *Care4myHeart*.

Methods

Methodology

This research was informed by the Design Science Research Cycles proposed by Hevner [13] and refined by our research team [14]. Hevner's framework consists of three cycles: design; relevance; and rigour. The relevance cycle consists of context-specific inputs from the environment and the rigour cycle incorporates theories and methods from the existing knowledge base [13]. Data from both cycles were incorporated into the design cycle where the innovation was developed and iteratively refined [13].

Design Process

The systematic design and development followed Stanford University's Design Thinking process of innovation [15]. The five-stage process enlisted incorporated empathising with stakeholders, defining the healthcare challenge, ideating possible solutions, creating a rapid prototype, and testing with end-users [15]. Embedded in the research is co-design. Co-design is a design-led process incorporating creative and participative principles and tools to actively involve a diverse group of stakeholders to explore, develop and test solutions to shared challenges [16]. Clinicians, patients and family caregivers were recruited from our health service, a large metropolitan tertiary hospital campus specialising in cardiac care in metropolitan Sydney, Australia. Clinicians included two Nurse

Practitioners, a nurse consultant, dietitian, physiotherapist, pharmacist and a cardiologist. Design activities were led by a cardiac Clinical Nurse Specialist and occurred on the hospital campus or via email as required. Ethical approval was granted from the University of Tasmania and St Vincent's Private Hospital Sydney. Firstly, we present the design processes enlisted in the empathise and define phase, followed by creative, dynamic processes within the ideate and prototype phase.

EMPATHISE AND DEFINE

Interviews were conducted with seven patients, four family caregivers and seven clinicians to identify experiences, challenges and opportunities regarding the lived experience of the main stakeholders. The following design artefacts - material objects that can be viewed by others, used to challenge perceptions and inspire new ideas [17] – were created by the research team from analysis of the data:

(1) Journey map – a list of daily self-care activities and associated emotional responses;
(2) Stakeholder map - personal and professional persons involved in self-care;
(3) Personas - four diverse characters representing patient needs and insights [18];
(4) Current care summary - health professionals critique of self-care support [19]; and
(5) Clinical relevance information - considerations for the effective implementation of the mHealth app [19].

The design brief was developed by the research team (authors 1, 2, 4 and 5) from analysing the design artefacts. It is a result of the composite of the design artefacts as interpreted by the research team. The design priorities within the brief were to: i) address medication and symptom management challenges; ii) involve some form of self-care plan; and iii) manage all stakeholders in care, as well as being evidence-based, useful, simple and easy to use [19].

IDEATE AND PROTOTYPE

A subset of eleven participants representing each of the three stakeholder groups (7 clinicians, 3 patients, 1 family caregiver) participated in two workshops and four months of iterative prototype development in 2017 [20]. This subset of participants will hereafter be referred to as 'co-design team members'. Firstly, design artefacts were actively used in timed and focused group activities within the workshops resulting in a storyboard of the initial design on a whiteboard. Thereafter, individual co-design team members met with the design lead to refine the prototype referring to the design artefacts and other resources as required. A recurrent analysis of the academic literature, local policies, national guidelines, standards, online resources and self-management tools ensured consistency with the evidence-base. Co-design team members identified these resources as needed and referred to them intermittently throughout the development. The skills, knowledge and experience of each co-design team member was incorporated in version updates which involved an ongoing and collaborative negotiation between co-design team members to decide on content. The final software version reported in this paper represents the outcomes of the design cycle as the team's collective decisions regarding the features and functions of the app.

Results

The findings elicited throughout the co-design process are reported alongside each app component in a justification of the final app design. First, we present an overview of the app and thereafter describe the app's three main sections.

Design overview

Care4myHeart is an evidence-based, modular, patient-facing consumer mobile health application for Android and iOS. The application interface consists of three main sections: (i) the *home screen*; (ii) the *health management* section; and (iii) the *My Plan* section. The home screen is the initial contact with the app's interface and contains the priority and daily components of HF self-management, reminder summary, general information on the condition and a settings tab (see figure 1). As much of the self-management work for patients with long term conditions is associated with management of medical documentation, medical appointments and healthcare team interactions, health management tools are included in the app's design and are reported under the heading *health management* (see boxed sections, figure 1). The *My Plan* section includes nine components of HF self-management and the favourites option (see figure 2).

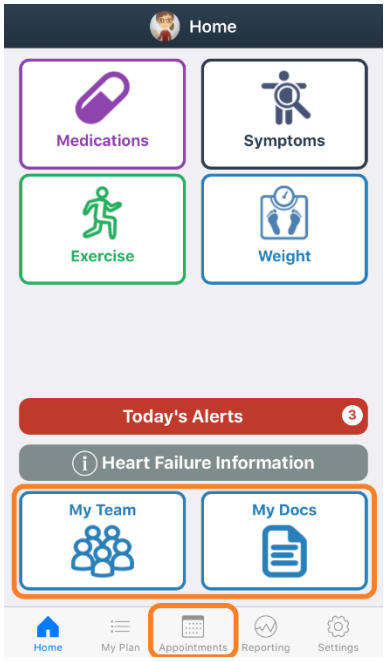

Figure 1: The *Care4myHeart* home screen including the health management section (boxed in orange).

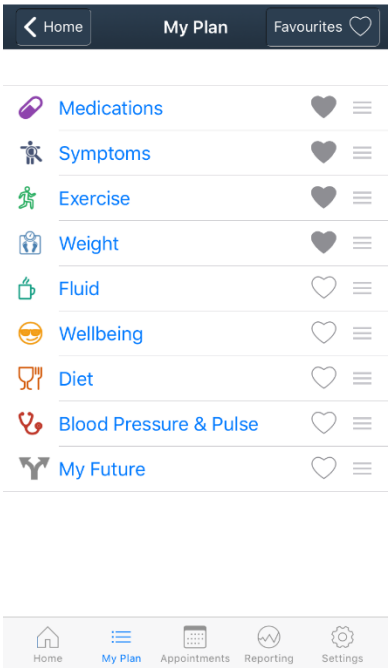

Figure 2: The *My Plan* section.

The three main sections of the app are described below with a description of the rationale behind the design.

Section 1: Home screen

Table 1 presents the home screen design which comprises the *My Plan* sub-section, heart failure information, today's alerts and settings.

Table 1: Care4myHeart's home screen design and rationale

Sub-section	Item	Rationale
My Plan icons	• Nine self-management components • 'Favourites' appear on home screen	• Design priority to involve some kind of self-care plan • Clinicians wanted individualised care plan which involves the patient and family • Standards [21] and recommendations [7] for the ongoing management of HF
Heart failure information	• Information pages: overview, symptoms and treatments	• Design priority to have an evidence-based resource that would be useful, simple and easy to use • Clinicians wanted early, regular, clear, appropriate, basic and needs-based educational material • Health literacy considerations • The credible source for the information was the St Vincent's Health website [22]
Today's alerts	• List of tasks to be completed	• The literature highlights the key measures to track in HF and the importance of setting self-care goals [23-25]

Settings	• Enter baseline data and set goals	• The team referred to the key measures to track in HF and recommendations to set self-care goals [23-25]

MY PLAN

The *My plan* sub-section is based on the principles within the Australian standards [21] and recommendations [7] for the ongoing management of HF which emphasise the need for self-care education and support [7]. The core requirements of these standards are the provision of clear and reliable information on symptoms, exacerbating factors and both medical and lifestyle management [7]. The benefit of *My Plan* sub-section is the modular approach providing an option as to which sub-sections are pertinent, in appreciation that individually-tailored management plans are recommended as a tool to support care coordination [21] and optimise wellness. For relevance to the healthcare context, clinicians believed individualised care planning could be improved in current practice with a key design priority to involve a self-care plan. The favourites function – allowing users to select their individual priority *My Plan* components – displays important self-management sub-sections on the home screen. Having favourites displayed on the home screen was especially relevant as it actively facilitates the involvement of patients and family in individualised care planning during the set-up process, through choice of components from the *My Plan* list *and* number of components based on their preferences and goals.

HEART FAILURE INFORMATION

HF information, written in plain English including an overview of the condition, common symptoms and treatments, is found via a button on the home screen accessible by patients and their family. The information was sourced from the St Vincent's Heart Health website [22] and deemed an appropriate inclusion by clinicians and patients alike. The HF information section provides an opportunity to communicate educational material in 'patient-friendly' language as a useful, clearly-displayed repository of evidenced-based information, as prioritised by clinicians and noted in the design brief. Clinicians recognised educational material for patients with HF should be given early, regularly and be clear, appropriate, basic and needs-based. Previous work with heath writers for the website content was discussed in the design workshops and so paragraph sizes were limited to 4-5 lines and large text sizes were used to improve readability for patients. Providing a HF information summary clearly visible on the home page was deemed important by the co-design team who often encounter family members asking for detail about the condition and its treatments.

TODAY'S ALERTS

A summary list of self-management tasks for the user to complete for the day (Today's alerts) was a priority design inclusion. Local clinicians believed follow-up with patients should be improved in current care to aid memory. Co-design team members considered reminders and scheduling important functions of the app to be addressed and are therefore included features in the alerts summary.

SETTINGS

Baseline self-management data and patient goals are personalised in the app's settings. Co-design team members prioritised patient ownership, interactivity and tracking as important for the user-experience. In the app's settings, the key measures to track [23-25] or goals to be set relate to weight, fluid restriction volume, blood pressure, pulse, daily steps and number of exercise videos to be viewed daily.

Section 2: Health management

The *health management* section of the app provides the opportunity for users to enter medical appointments into a calendar, digitally store medical documents and list contact details for all personnel involved in their care. The design and rationale is summarised in table 2.

Table 2: The health management section design and rationale

Sub-section	Item	Rationale
Appointments	• Add medical appointments including detail	• Patients experienced challenges managing multiple appointments with family caregivers often assisting • Clinicians believed follow-up and connected care is not done well in the health service • Scheduling and reminders were a priority • Reviewed current tools for documenting clinic and doctor visits [23, 25]
My Docs	• Store, review and share test results, letters and referrals	• Some patients wanted test results but may misplace documentation • Clinicians wanted to include or track data, facilitate team communication and maximise and join care • Reviewed tools to document health records [23, 25] • Hospital's discharge checklist contains echocardiogram results [21]
My Team	• Contact details of emergency contact person and health professionals	• Patients frequently liaise with their healthcare team but experience poor information sharing between healthcare providers • A design priority was to manage all stakeholders in care well and facilitate team communication • Referred to the recommendations [7] and standards [21] for multidisciplinary care in HF • The literature highlights the importance of team communication [24] and provides tools to document their contact details [23-25] • The hospital's HF discharge checklist contains post-discharge care and follow up details [21]

APPOINTMENTS

The appointments tab contains a calendar to add, review and set reminders for medical appointments with the ability to add detail needed for the appointment. The HF self-management literature lists the importance of keeping track of clinic and doctor visits [23, 25]. Locally, clinician's critique of current self-management support is that follow-up care and connected care is not done well and the co-design team prioritised 'scheduling and reminders' as design priorities. From the patients' perspective there were reported challenges managing multiple medical appointments as some choose to take notes immediately after appointments to summarise the conversation to capture the complexity of care. Especially necessary for those living in rural areas who need to travel for specialised medical care, careful coordination of appointments effectively could improve time

away from loved ones, avoid early wake-ups and missing meals or medication doses. Further, some family caregivers reported feeling like project managers, regularly assisting with scheduling and attending medical appointments causing feelings of being overwhelmed with caregiver responsibilities. These important patient- and family-centred considerations were incorporated in design improvements of the appointments section.

MY DOCS

The *My Docs* (documents) section provides an opportunity to store, review and share test results, letters and referrals. Documenting health records [23, 25] is important in managing one's health and the health service's HF discharge checklist contains echocardiogram results (Appendix F [21]) for effective communication when moving between care settings. During workshops the co-design team determined it was relevant to the patient persona who want to know echocardiogram and pathology results but may periodically misplace this documentation. From the perspective of clinicians, a design priority was to include or track patient data for the purposes of reviewing this data later. The *My Docs* section was seen to way for the patient to facilitate communication between the healthcare team, to better maximise and join care between healthcare providers and settings.

MY TEAM

My Team lists the contact details of the user's emergency contact person and the health professionals relevant to their care. The recommendations [7] and standards [21] for multidisciplinary care demonstrate the importance of patients engaging effectively with their care providers, through for example, communication with health professionals [24] and documenting their contact details [23-25]. The hospital's discharge checklist contains specific details regarding the person(s) responsible for post-discharge care and follow up in the community (Appendix F [21]). The *My Team* section was considered relevant by all stakeholders throughout the app's design. Patients may have an available and approachable multidisciplinary team, foster relationships with respect and trust with doctors/nurses in their healthcare team and care seek regularly. However, participants also reported poor information sharing between healthcare providers and may be unsure who else is providing care for them commonly relying on memory. The stakeholder map identified that the patient's spouse and general practitioner are the most likely personal and professional involved in HF self-management. Other members of the family and the pharmacist were also frequently involved, followed by a person's employer or friends and specialist. In terms of the relevance of the *My Team* section to healthcare providers, clinicians wanted a tailored care plan that includes the multidisciplinary care team to ensure that care was holistic, and the design brief emphasises the importance of managing all stakeholders in care well. Clinicians communicated their concerns of health inequality as some patients have poor access to specific multidisciplinary team members. Finally, during design workshops the co-design team prioritised team communication as a priority function. These factors resulted in a group decision to include a list of names and details of all persons involved in the care of a person with HF.

Section 3: My Plan

The *My Plan* section includes nine sub-sections of heart failure self-management and the favourites option and is summarised in table 3. Each of the nine self-management sub-sections (listed in no particular order) were included because they are considered key in the ongoing management in HF and a relevant, useful and helpful inclusion by patients, family caregivers and clinicians. This is based on the local clinical service framework which supports that all patients with HF 'should have access

to individually tailored, disease management and rehabilitation services offered on an outpatient or community basis' [21[p29]].

Table 3: The *My Plan* section design and rationale

Sub-section	Item	Rationale
Symptoms	• Infographic of common signs and symptoms • Help seeking information • Understanding deterioration information	• Patients reported frequent, varied symptoms. Some were frustrated by multiple, interacting and complex symptoms and/or lacked understanding of the treatment rationale in lessening symptom burden • The design brief highlighted the importance of addressing symptom management challenges • The co-design team wanted information and self-help which is visual and simple • Source of the infographic was the St Vincent's Heart Health Website [22] • When deciding on the content for the information and advice pages, HF patient information booklets [23, 24], the St Vincent's Heart Health Website [22] and the chronic heart failure action plan [24] were referred to
Medications	• Medication, previous medications and allergy list • Medicine information • Diuretic plan	• Clinicians believed medication management should be better supported • Patients reported challenges with managing their medications with caregivers often involved • Medication information was an important design feature, with specific insights and expertise provided by the pharmacist • The team referred to HF medicine information in patient education booklets [23-25] which includes a medication list template [23], reviewed information on the National Prescriber Scheme MedicineWise website [26] and the flexible diuretic regime in the hospital's HF discharge checklist [21]
Fluid	• Visual representation of jug at volume of fluid restriction • User enters oral fluid intake throughout the day	• Patients experienced challenges with maintaining fluid restrictions • The co-design team wanted tracking with feedback and an interactive interface • Fluid-related HF information and advice [24, 25, 27], local guidelines [22, 27], tools/guidelines for documenting fluid intake [23, 25, 27] and previous qualitative research on fluid restriction adherence [28] were referred to when deciding on content
Diet	• Healthy eating • Low salt (sodium) eating including label reading and foods to avoid	• Patients wanted general information only • Caregivers often prepare meals

		• Specific insights and expertise were provided from the clinical dietitian on the co-design team • Information and advice on healthy eating including reducing salt [23-25, 29], the 'healthy eating' section of heart foundation website [30] were referred to during the design
Weight	• Record daily weight with 7-day graph • Interactive, colour-coded feedback and pop up alerts	• Patients may not be accurate or remember their daily weight • Clinicians wanted to include or track HF-related data in an interactive, visual and tailored format • The cardiac nurse consultant mainly designed the feedback system • Information on fluid retention including documenting daily weight and guidelines for help seeking were referred to [23-25, 27]
Blood pressure (BP) & Pulse	• Record and store blood pressure and pulse measurements	• A patient suggested this sub-section and the cardiologist supported its inclusion • Patient booklets supported intermittent documentation of blood pressure [23, 25] and a recent BP and pulse is included in the hospital's HF discharge checklist [21]
My Future	• Information and prompts to *decide* on a plan, *discuss* this with others, speak to your *doctor* and plan what happens to your *defibrillator*	• Clinicians suggested the inclusion of information on advance care planning • The team referred to the local advance care planning website [31] and palliative care recommendations [7]
Wellbeing	• Interactive depression screening tool • 'At risk' or 'low risk' results screen	• This sub-section was suggested by a patient • Patients frequently reported anxiety and worry • Emotional support was a priority function • The team reviewed the local depression screen tool (PHQ2 score) in use at the hospital [32, 33] and reviewed psychological care recommendations for HF [7]
Exercise	• Step counter with 7-day graph • 3x exercise videos demonstrated by physiotherapist (balance, upper limb and lower limb) with 7-day graph	• Patients reported using their smartphone's step counter, appreciated supervised physical exercise and set their own exercise goals • Clinicians wanted to include or track data • The physiotherapist designed the exercise program, using the Otago exercise programme [34] as a guide

SYMPTOMS

The symptoms section includes an infographic containing the common signs and symptoms of HF, information to assist in appropriate help seeking and information about worsening HF. This sub-section was an important inclusion in the app because patients frequently reported symptoms such as breathlessness, urinary frequency, sleep disturbance, fatigue, exhaustion, and night-time breathlessness, anxiety and agitation. Patients said they were frustrated by multiple, interacting and

complex symptoms. Other patients lacked understanding of the treatment rationale in lessening symptom burden. During workshop activities the co-design team decided it was a design priority to include information and self-help in a visual and simple format. The infographic representing common HF symptoms was sourced, with approval, from the St Vincent's Heart Health Website [22]. Hyperlinks to further information and advice pages are accessed through this infographic and was collated from patient information booklets [23, 24], the St Vincent's Heart Health Website [22], the chronic heart failure action plan [24] as well as the multidisciplinary team members themselves based on their clinical experience and expertise.

MEDICATION

The medication component includes a list of current medications, previous medications, an allergy list, medicine information and the patient's own diuretic plan. Clinicians thought it appropriate to facilitate improved medication management as a component that should be improved in current care. The pharmacist on the co-design team provided specific insight into the design of this sub-section. Patients reported the disruption to their routine when medication prescriptions were changed and the inconsistent documenting of medication lists with some writing changes on scrap paper or even forgetting important changes in the reality of daily life. Family caregivers are sometimes involved in reminders and patients reported taking tablets with them during outings, so these realities of the daily management of medications were incorporated into the design of this sub-section. During workshop activities where the sub-section was further refined, co-design team members prioritised medication information as an important design feature. The cardiac nurse consultant regularly caring for Indigenous people saw value in including the colour of the medication as a visual reminder. In regard to the literature, medication is a reported important component of HF self-management as per the information contained within the patient education booklets [23-25] which provides a written medication list template [23] and by the hospital literature with the flexible diuretic regime listed in the hospital's heart failure discharge checklist (Appendix F [21]). The National Prescriber Scheme MedicineWise website [26] was also reviewed for general medicine information.

FLUID

The fluid sub-section comprises the important fluid restriction guideline for HF. The page displays a visual representation of a measuring jug at the volume of fluid restriction tailored to the patient's restriction volume in the settings (commonly 1200 or 1500ml per day). The jug gradually fills as users enter oral fluid intake throughout the day. Restricting fluid intake is likely the most important method to prevent fluid congestion alongside taking diuretic medications however patients commonly reported challenges with maintaining fluid restrictions in daily life, especially with thirst. Clinicians wanted to include or track data, and during design workshops the co-design team emphasised that user feedback and an interactive interface were important. Information and advice [24, 25, 27], local guidelines [22, 27], and tools/guidelines regarding documenting fluid intake [23, 25, 27] were local and national literature sources considered during the design. Previous qualitative research conducted in the same clinical setting regarding fluid restriction adherence was also referred to [28].

DIET

The diet component includes information for healthy eating, low salt (sodium) eating, label reading and foods to avoid. Patients reported that they were not necessarily interested in calorie counting so general information and advice on healthy eating including reducing salt [23-25, 29], recipe

suggestions and the 'healthy eating' section of Heart Foundation website [30] were consulted. These resources were deemed relevant to family caregivers who commonly prepare and/or assist with meal planning and cooking. Recommendations, advice and insight regarding nutritional education was provided by the clinical dietitian on the co-design team.

WEIGHT

Daily weight management in the weight sub-section of the app gives the user the ability to record daily weight, view a 7-day weight trend on a bar graph, receive colour-coded feedback based on this data and pop up alerts depending on stability of that day's weight in comparison to the dry weight set in the settings tab. Information on fluid retention including documenting daily weight and guidelines for help seeking [23-25, 27] throughout the literature were consulted, alongside specialist input from the two Nurse Practitioners on the co-design team who regularly assist in managing the variations in weight due to fluid congestion in worsening HF. The patients interviewed had variable understandings regarding fluid management, reporting what they knew about dry weight and the concern about going 2kg over their dry weight. Clinicians thought the weight section was highly important to include in the apps design, specifically around tracking weight data over the longer term. The co-design team believed having an interactive and visual interface that was tailored to patient parameters improved its utility. The nurse consultant was particularly involved in the colourful design of the feedback alert system when weights varied from the dry weight.

BLOOD PRESSURE AND PULSE

For some, self-monitoring of blood pressure and pulse is important in HF. This *My Plan* sub-section provides the option to record and store blood pressure and pulse measurements. Clinicians generally supported the inclusion of patient data to track however the inclusion of recording blood pressure and pulse specifically, was inconsistent. One patient initially suggested the inclusion and the cardiologist agreed however other clinicians believe it was not important enough to include especially comparative to other, daily measures to track in HF. A second patient who does not self-monitor this data did not see it necessary to include in the app. Through ongoing discussions it was decided this sub-section would be included in the final design as the literature supports the intermittent documentation of blood pressure [23, 25]. Further, the hospital's discharge checklist specifies recording a postural blood pressure (measurements taken while sitting and standing) and nature of the pulse as either regular, irregular or paced (Appendix F [21]).

MY FUTURE

The *My Future* sub-section relates to the long-term planning required for patients with HF. This section contains information and prompts to decide on a plan, discuss this with others, speak to their doctor and plan what happens to their defibrillator (an implantable medical device) if they have one. The inclusion of this section was deemed relevant by clinicians and patients on the co-design team agreed to its inclusion without providing specific input into its content. The team reviewed the local advance care planning website [31] and palliative care recommendations for the multidisciplinary care of people with HF [7] as key literature sources.

WELLBEING

The wellbeing component represents the psychological aspect of self-management. It contains an interactive depression screening tool, 'at risk' or 'low risk' results screens and information and advice pages. This section was suggested by a patient on the co-design team during the second design workshop as they felt it necessary to address the emotional support needed for people with living with HF. In interviews patients reported the frequency of anxiety and worry. Patient needs

included family, nature, mindfulness and happiness demonstrated in one patient persona who balances quality of life with safety in HF in her pursuit to maintain wellbeing. The co-design team then conducted a literature review of the psychological care recommendations for HF [7] and clinicians communicated their use of the depression screen tool (PHQ2 score) [32, 33] routinely used in current practice. The PHQ2 store is a two-item validated questionnaire designed for the initial assessment of depression and anxiety in the primary care setting [32, 33] and precedes referral for specialised care in the local hospital setting.

EXERCISE

The exercise component has a step counter with 7-day graphical representation of daily steps. Three exercise videos demonstrated by physiotherapist– balance, upper limb and lower limb – with a 7-day graph is included. Patient interviews uncovered that patients were using their smartphone's step counter, appreciate supervised physical exercise and set exercise goals, for example one patient setting a 2km daily walk. Clinicians valued ability to track patient data in considering the relevance to the patient group and physiotherapist on the co-design team designed the exercise program to the specific context. The Otago exercise programme to prevent falls in older adults [34], a resource commonly referred to for this patient population, formed the basis of the content of the balance and lower-limb exercises.

Discussion

We have presented the final design of the *Care4myHeart* app which includes the home screen, a health management section and *My Plan* section. With the goal to support local patients with HF self-management and representing the opinions and perspectives of those who would use or recommend the novel app, we enlisted a co-design methodology. The strength of the context-specific co-design process to elicit the final design was the access to, and ongoing involvement of, key stakeholders and the relevant literature. However, the strength of context-specificity is also a limitation to portability, and the final design is limited to the stakeholders involved in its development. These key strengths and limitations are explained in the discussion sections below.

Strengths of the co-design process to achieve the final design

The greatest strength of the co-design process to achieve the design outcomes was the involvement of clinicians, patients and family caregivers. Drawing on best practice, the literature supports using collaborative, team-based processes to develop mobile health interventions [35]. The benefit of the approach to design was strategically coordinating stakeholder involvement within each development stage. As we progressed from the empathise and define phase to the ideate and prototype phase we were able to achieve the intermediate design goals to input into the subsequent phases, ensuring efficiency of development to achieve the final design.

Firstly, in the empathise and define phase, stakeholders were individually interviewed to understand their experiences, ensuring perspectives and opinions were appropriately defined. Appreciating the various interests of different stakeholders [35] by interviewing patients, caregivers and clinicians separately ensured a good understanding of healthcare challenge to be addressed in the design from many different standpoints. However, it was the careful emphasis on the 'define' phase - where these experiences were visually represented in poster format - which facilitated cross-stakeholder empathy. Referred to as a mutual learning [36], knowledge transfer between different stakeholders was maximised [35] in this process. Patient personas were a way to represent the important healthcare consumer voice, as patients are often passive in healthcare improvement activities [37]

and traditionally excluded from design efforts [17]. It has previously been shown that benefit of documenting patient narratives on preferences, beliefs and values is that it legitimises their preferences [38]. Equally, it was important to interview caregivers in HF, who in other settings have expressed distrust towards the health system due to feelings of role strain [39]. As a vessel for positive change in healthcare, the empathise and define phase in co-design presents a method of inclusion and mutual respect, ensuring that for caregivers (and indeed all stakeholders) are 'more explicitly involved in the design of disease-management interventions' as recommended by Burke and colleagues [39^{p736}]. The benefit of representing stakeholder experiences separately gives relevance to their specific needs and insights to be considered in the subsequent design stage.

Secondly, bringing stakeholders together was beneficial in the ideation phase for a fit-for-purpose design. Collaborative practices support design features that would be accepted by potential users and are technically feasible [35]. As suggested by Skeels and Pratt [36] the role of team members as 'partners' in the design process was emphasised in our design process, allowing for the creation of a collaborative group dynamic where participants addressed each other directly [36] in design workshops. However, in this research we were limited by the small number of patients who chose to attend the workshops. To account for this, design activities included the use of the design artefacts, commonly used in design workshops as a design strategy to provoke an alternate way of thinking, challenge perceptions or raise questions about conventions and assumptions [17]. Design artefacts were considered a practical tool for co-design, spurring creativity and supporting meaningful participation [16] through discussion and collaborative decision-making to achieve the conceptual design of the app by the end of the second workshop.

Finally, in the prototype phase all stakeholders provided feedback independently to refine the wireframes. The overarching principal was that the design reflected the ideas generated by the group [36] even though stakeholder involvement was done individually. Content was written by clinicians with the relevant expertise, checked by patients for clarity, and iteratively refined until consensus was achieved. One-to-one feedback sessions facilitated a hands-on assessment of the digital prototype version for review. To maximise honest feedback and in appreciation of their voluntary participation, the nurse-lead offered a safe, respectful and relaxed environment. Updating the prototype quickly meant they were engaged and valued in the creation of the innovation.

Another noteworthy contribution of this research was incorporating the literature, guidelines and current practices into the design which strengthened the relevance of the app to the healthcare context. Clinicians aspired to develop this app as a self-management tool to be an adjunct offering in addition to existing HF care. To support clinicians in providing the expert care they aspired to provide, they were unanimous it needed to include the locally-relevant evidence-based information and be consistent with the self-management support literature they provide. The app aimed to supplement (not replace) other, traditional formats of patient education (for example patient information booklets [23-25]) as interventions that emphasise and reinforce the complexity of HF have been considered particularly valuable [4]. Anderson and Emmerton [5] suggest pairing app interventions with healthcare professional input, advising against 'leaving consumers to their mobile devices without periodic check-ups' [5^{p594}]. The purposeful integration of the app to the healthcare setting is undoubtedly more likely to be achieved if it is developed within an existing healthcare environment, with only 2% of existing consumer mHealth apps connecting and communicating with provider health systems [10]. Embedded practices and policies were therefore incorporated from early in the app's design to ensure consistency with the local execution of evidence-based care.

Limitations of the co-design process

The outcomes of the design are limited by the stakeholders involved in the project. Each person had a role to play to positively impact the final design but also the potential to limit the design. For example, the nurse-lead who facilitated the design activities had limited design experience and thus learned co-design processes as the project developed. A skilled facilitator in co-design chooses the right tools and provides the right environment to engage and inspire [16]. Also study participants were drawn from local clinicians, patients and family caregivers who were a self-selecting group of volunteers. Therefore, the design outcomes are based perspectives from this limited, context-specific group of stakeholders, which would have biased the findings. From an organisational point of view, the hospital/university venture needed to be formalised as a research project which had implications on recruitment. In this case, ethical approval was required to obtain patient and family caregiver participation which means that not all target end-users could be involved. Recruited participants were those with adequate literacy to understand the information sheet and consent form, and confidence to collaboratively engage with various stakeholders, many of whom are in positions of power in the healthcare setting. Future co-design projects should incorporate more diverse patient and family caregiver perspectives to ensure the health technology is relevant to as many consumers as possible and not limited in relevance to a homogeneous patient population.

The strength of context-specificity is also a limitation of the portability of the design. Australian policy and current practices and procedures were included to address the needs of the local healthcare environment. Therefore, extra work in the design will be required to make the app relevant outside of the community in which it was designed, to be aligned with other healthcare environments and consumer needs.

Future directions

The first step is assessing patients' acceptance of such a tool to their current lifestyle. This research team has undertaken a usability study aimed to understand the experience of using the app with new subset of patients not involved in the design phase. Findings from the usability study will determine other features for inclusion in the next version and provide implications of consumer mHealth apps to self-management practices.

Co-design processes for context-specific digital health, particularly with the involvement of multiple stakeholders, should be evaluated for effectiveness. Currently, researchers are interrogating the process from the perspective of co-design participants and the nurse-lead.

Conclusion

In this paper the final, modular design of the consumer mHealth app for heart failure, *Care4myHeart*, was presented with the rationale associated with each app section and sub-section. The design outcomes were elicited from a co-design process incorporating the active involvement of patients, family caregivers and clinicians together with the local literature. In planning for utility and acceptability, health app development teams should strategically incorporate relevant stakeholders and literature to design mobile health solutions which are rigorously designed from a solid evidence-base and relevant to those who will use and recommend their use.

Acknowledgements

The authors would like to acknowledge the patients, family members and clinicians for contributing their time and feedback in the development process. This research is supported by a St Vincent's Clinic Foundation grant and a scholarship from the District Nurses, Hobart.

Abbreviations

App	Application
BP	Blood pressure
HF	Heart failure
mHealth	Mobile health

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6.3 Preface to Publication 8

Publication 8 presents the 14-day usability study conducted with a new subset of local patients with heart failure and addresses Research Objective 3: To understand the patient experience using the app for heart failure self-management.

Consumer apps are seldom evaluated by research, so rigorous usability studies on the implications to behaviour change are needed. Usability studies present an opportunity to report positive and negative patient experiences, adding to the knowledge base on user-centred design for the benefit of other development teams. Collectively, usability studies contribute to the understanding of the behaviours of healthcare consumers for traditional and technology-based interventions for disease self-management.

JMIR Human Factors was the chosen publisher for Publication 8 as the journal publishes usability studies of innovations and technology used for health. JMIR Human Factors is an open access journal with a wide readership. In appreciation, the St Vincent's Clinic Foundation has financially contributed by paying the article processing fee associated with this open access publication. The publication adds to the existing knowledge base reporting the real-life experiences of using a mHealth app in the home setting by patients with heart failure. Notably, the contribution further expands the phenomenon surrounding the behavioural implications between humans and health technologies.

Publication 8 citation is as follows:

> Woods, L.S., Duff, J., Roehrer, E., Walker, K., & Cummings, E. (2019). Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study. *JMIR Human Factors*, *6*(2), e13009. doi:10.2196/13009 Published and reproduced under the terms of Creative Commons Attribution licence 4.0. The publication is available at JMIR Human Factors through http://humanfactors.jmir.org/2019/2/e13009/

6.4 Publication 8: Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study

See next page.

Original Paper

Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study

Leanna Sarah Woods[1,2], BN (Hons), Grad Cert Nurs; Jed Duff[3], BN, MN, PhD; Erin Roehrer[4], BCom, BIS (Hons), PhD; Kim Walker[1], BAppSci, PhD; Elizabeth Cummings[1,5], BA, BIS (Hons), PhD

[1]School of Nursing, University of Tasmania, Darlinghurst, Australia

[2]St Vincent's Private Hospital Sydney, Darlinghurst, Australia

[3]School of Nursing and Midwifery, University of Newcastle, Newcastle, Australia

[4]School of Technology, Environments and Design, University of Tasmania, Hobart, Australia

[5]School of Health Information Science, University of Victoria, Victoria, BC, Canada

Corresponding Author:
Leanna Sarah Woods, BN (Hons), Grad Cert Nurs
School of Nursing
University of Tasmania
1 Leichhardt Street
Darlinghurst, 2010
Australia
Phone: 61 0285727930
Email: leannaj@utas.edu.au

Abstract

Background: To support the self-management of heart failure, a team of hospital clinicians, patients, and family caregivers have co-designed the consumer mobile health app, *Care4myHeart*.

Objective: This research aimed to determine patient experiences of using the app to self-manage heart failure.

Methods: Patients with heart failure used the app for 14 days on their own smart device in a home setting, following which a mixed-methods evaluation was performed. Eight patients were recruited, of whom six completed the Mobile Application Rating Scale and attended an interview.

Results: The overall app quality score was "acceptable" with 3.53 of 5 points, with the aesthetics (3.83/5) and information (3.78/5) subscales scoring the highest. The lowest mean score was in the app-specific subscale representing the perceived impact on health behavior change (2.53/5). Frequently used features were weight and fluid restriction tracking, with graphical representation of data particularly beneficial for improved self-awareness and ongoing learning. The use of technology for self-management will fundamentally differ from current practices and require a change in daily routines. However, app use was correlated with potential utility for daily management of illness with benefits of accurate recording and review of personal health data and as a communication tool for doctors to assist with care planning, as all medical information is available in one place. Technical considerations included participants' attitudes toward technology, functionality and data entry issues, and relatively minor suggested changes.

Conclusions: The findings from this usability study suggest that a significant barrier to adoption is the lack of integration of technology into everyday life in the context of already established disease self-management routines. Future studies should explore the barriers to adoption and sustainability of consumer mobile health interventions for chronic conditions, particularly whether introducing such apps is more beneficial at the commencement of a self-management regimen.

(JMIR Hum Factors 2019;6(2):e13009) doi:10.2196/13009

KEYWORDS

heart failure; mobile health (mHealth); mobile apps; usability study; Mobile Application Rating Scale; patient experience; self-management; mobile phone

Introduction

Heart failure affects at least 26 million people worldwide [1], including more than 1 million Australians [2], and its prevalence is expected to rise [1]. This complex, highly symptomatic syndrome is associated with high health care costs, high readmission rates, and poor clinical outcomes [3]. Targets to improve functional outcomes, psychosocial outcomes, burden of care, and survival of patients with heart failure have resulted in a call for safe, person-centered, evidence-based action [3]. It is especially necessary to ensure equity of care for all patients through the efficient use of resources as well as support to empower patients and caregivers in long-term care [4].

Self-management support, specifically for nonpharmacological requirements, is critical to the effective management of heart failure [2] and is often delivered through educational measures [3,5,6]. Appropriate self-management of heart failure involves daily weight monitoring, fluid restriction, dietary modifications, and exercise alongside regular monitoring and follow-up [2]. In the home setting, recording and recognizing changes such as increased weight, fluid retention, and worsening symptoms, which are indicative of worsening heart failure, can allow patients to get help early [6]. However, challenges with translating guidelines into practice put patients at risk of suboptimal care [2], with the complexity of self-management of heart failure contributing to poor adherence [7].

Rapid improvements in computing capability paired with the popularity of mobile phones in our communities provide more opportunities in health care delivery [7]. Due to this potential, mobile health (mHealth) interventions for heart failure continue to expand; however, this expansion is accompanied by challenges in technology adoption. Reliability of equipment [8], limited technical support [8], cognitive impairment [9], and variable interest in self-recording of health measurements [9] are a few factors affecting use in this patient population. Older people, who have a prevalence of heart failure three times greater than that of the general population [10], have variable levels of willingness to adopt technology [9]. They may lack confidence in their knowledge of heart failure and rely on informal and formal caregivers for guidance [9]. Perceived usefulness and ease of use are considered the most important factors for mHealth adoption [11]. This poses specific challenges when designing interventions aimed to engage patients in self-management of heart failure and highlights the importance of using patient perceptions in newly developed interventions. Further, in a recent review, of the 34 consumer apps targeting heart failure on the commercial app stores, only 3 were evaluated in peer-reviewed articles [12], indicating the importance of disseminating research findings to advance consumer mHealth.

This study is part of a larger research program where *Care4myHeart*, an mHealth app for self-management of heart failure was developed in our hospital by a team of clinicians, patients, and family caregivers. The diverse group of stakeholders collaborated to design an app that was relevant and useful to target users and consistent with the evidence-based heart failure guidelines. The aim of this paper was to explore patients' experiences of and feedback after using the app.

Specific research questions were as follows:

1. What were the patients' experiences of using the *Care4myHeart* app?
2. What is the perceived impact of the app on self-management of heart failure?

Methods

A 14-day usability study was performed using a mixed-methods evaluation to determine patient experiences of using the mHealth app for self-management of heart failure.

Participants

Self-selecting participants were recruited from cardiac inpatient units at a metropolitan private hospital in Sydney, Australia, via posters and flyers located in common patient areas. Medical and nursing staff members were informed of the research and referred patients who voiced their interest in participating. We included English-speaking individuals with heart failure who were not highly dependent on medical care, resided at home, were able to provide feedback, and owned a smart device capable of housing the app. Participants were excluded if they were involved in the co-design of the app, were cognitively impaired, or were otherwise unable to use the app. We aimed for a sample size of 8-10 participants, because up to 80% of usability problems can be identified by this number of users [13].

Intervention

Details of the co-design process of the mHealth app are reported elsewhere [14-17]. The final design of the self-management app has three main sections: *Home screen*, *My Plan*, and *Health Management*. The *Home screen* provides a shortcut to the priority *My Plan* icons based on patient goals, and a reminder summary. The *My Plan* section includes nine important components of self-management of heart failure: medications, symptoms, exercise, weight, fluid, well-being, diet, blood pressure and pulse, and future plans. A *Health Management* section contains a medical documentation repository, appointment calendar, and health care professional contact details. The app provides the opportunity to collect, track, and evaluate patient-entered data. Reminders, alerts, infographics, videos, health professional advice, and information pages throughout the app aim to guide patients to manage their heart failure. Sample user interfaces demonstrating the home, weight, and fluid restriction screens are presented in Figures 1, 2, and 3, respectively.

Figure 1. Sample home screen.

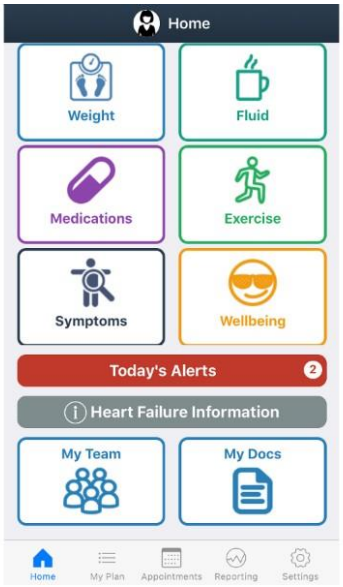
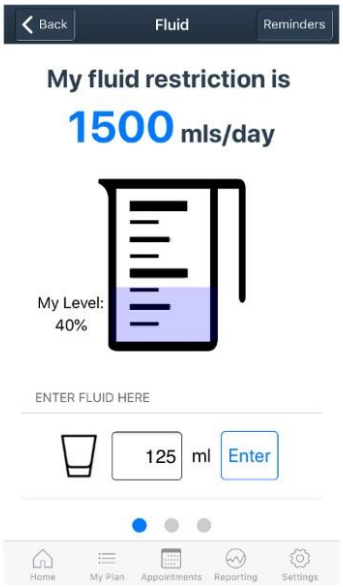


Figure 2. Sample weight screen.

Figure 3. Sample fluid restriction screen.



Study Procedures

The *Care4myHeart* app was downloaded to patients' own iOS or android smartphone or tablet device after procedures were explained and patient consent was obtained. A researcher spent 10-30 minutes providing an overview of the app interface, assisted with completing the personalized settings (dry weight, daily fluid restriction volume, daily step count aim, physical activity goals, and reminders), and determined self-management priorities based on patient preferences. Participants were asked to use the app as frequently as required to assess its usability, aiming for at least daily use over a 2-week period. Participants were encouraged to contact the research team by phone or email if they encountered problems or had questions throughout the study. For quality and safety reasons, participants were instructed to continue with their regular care regime in collaboration with their health care providers. Ethical approval for this study was obtained from the University of Tasmania and St Vincent's Private Hospital Sydney.

Data Collection

As soon as practically manageable after the completion of a 14-day period, participants reported their experience of using both qualitative and quantitative methods.

First, participants were asked to complete the Mobile Application Rating Scale (MARS) [18] either electronically (sent via email) or on paper (sent by post or completed in person during the interview). The 23-item MARS is a multidimensional measure of the four objective app quality indicators: engagement, functionality, esthetics, and information (which together form the overall app quality score). In addition, it includes a subjective quality subscale [18]. As *Care4myHeart* was not available in the app stores during the time of the study, we modified the MARS to 19-items, excluding four items because they were not applicable: accuracy of app description (item 13), goals (item 14), credibility (item 18), and evidence base (item 19). These items were removed from the mean score calculation as per the guidelines [18]. A supplementary, modifiable "app-specific" section assessed the perceived impact of the app on users' target health behaviors [18], in this case, improved heart failure self-management. MARS items are scored on a 5-point Likert scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent) [18]. The version used for this study is provided in Multimedia Appendix 1.

Second, participants were asked to attend an interview on the hospital campus or via phone, depending on patients' preference. A semistructured interview schedule included questions such as "What worked well and what could be improved?" "What functions did you use and why?" and "Would this application impact the way you look after your health?" Participants were given the opportunity to share experiences, communicate thoughts, and voice perspectives through open-ended and probing questions. App use was self-reported by participants themselves, as no usage data were collected in this study. Data were collected in June and July 2018.

Data Analysis

Data were de-identified and treated confidentially. MARS data were managed in the database software program Excel (Microsoft Corp, Redmond, WA), with mean scores produced by calculation of participant subscale scores. Interviews were transcribed verbatim and thematically analyzed using Braun and Clarke's process [19]. The process involved familiarization of the data through re-reading transcripts (Step 1), generation of initial codes and writing them directly on the transcript segments considered interesting or meaningful to the analyst

(Step 2), organization of codes into potential themes (Step 3), review of themes through checking and generating a thematic "map" (Step 4), generation of clear definitions and names for each theme (Step 5), and production of the report with compelling examples through a final analysis (Step 6) [19]. Data analysis in Steps 1 and 2 was conducted by the lead author (LW). Steps 3 to 6 were performed visually and collaboratively, with the themes confirmed by group discussion with the coauthors.

Results

Participant Characteristics

Eight participants consented and commenced the usability study. All participants were male (n=8), most lived with a spouse/partner (n=7) and were currently employed (n=5), and more than half resided in a rural location outside the metropolitan area (n=5). The average age of participants was 69 years (range: 61-84 years).

One participant discontinued the study after reporting technical challenges with a software update that occurred during the 14-day period. A second participant died prior to the final interview and collection of the MARS. Six of the eight participants completed the study with the survey and interview. The interview length ranged from 18 to 29 minutes.

Mobile Application Rating Scale App Quality Scores

Table 1 presents the four subscale scores (engagement, functionality, esthetics, and information), which make up the overall quality score, as well as the subjective quality score (representing satisfaction) and app-specific score (representing behavior change).

The overall app quality score was 3.53 of 5. Of the four subscales, the highest scores were for esthetics (3.83) and information (3.78), followed by engagement (3.37) and functionality (3.33); all scores were above the minimum acceptability score of 3.0. The highest-scoring individual items were layout (4.17), visual information (4.17), interest (3.83), and quality of information (3.80). The lowest scores per item were for performance (2.67), customization (3.00), and interactivity (3.00).

The subjective quality subscale representing app satisfaction scores showed an average of 3.29 of 5. Most participants would use the app more than 50 times in a 12-month period (n=7) and recommend the app to people who might benefit from it (n=4), but would not pay for the app (n=4). The mean star rating, comparable to the star rating on the app stores, was 3.33.

The lowest mean score was in the app-specific section representing the perceived impact of using the app on health behavior change (2.53). The app may have some impact on increased awareness regarding self-management of heart failure (3.17) but was rated "poor" on the perceived impact of the app on attitude, intention to change, help seeking, and overall behavior change (2.33).

Interview Findings

Analysis of interview transcripts resulted in 3 themes and 10 subthemes (Textbox 1).

Theme 1: App Use

Most participants used an android device (smartphones: n=2, tablets: n=2) and two used iPhones. Five participants had both a smartphone and a tablet device. Tablets were kept at home, and smartphones were not necessarily used for internet access. However, those who carry their smartphone in their pocket saw the benefit in data entry throughout the day. iOS users spoke about using their device with greater understanding and confidence than Android users in our sample; the former were also the two youngest participants. Patients self-reported app use for an average of 5-10 minutes once or twice a day on most days during the usability study. The app was used independently without family member involvement. Usage over the 14-day period decreased once users determined what was useful; however, version updates improved technical issues, with usage reportedly increasing after the updates.

Weight, Fluid Restriction, and Step Counter

The weight and fluid restriction sections were most frequently used. The quick speed of recording weight and weight alerts was highlighted as positive features. One participant described how beneficial the fluid recorder was:

> *The most beneficial feature for me at this point in time is the fluid intake...the fluid counter is excellent. I love it, absolutely love it.* [P8]

Fluid volumes were entered either throughout the day or at the end of the day in the fluid restriction section of the app:

> *I wouldn't put in fluid every time I had 100ml of fluid - I put it all in at the end of the day.* [P7]

Some found the app more convenient for self-management of fluid restriction than traditional means of recording fluid volumes because it was portable:

> *Beforehand what I was doing I had a measuring cup...I think the app is more friendly for me to use...I've got that in my pocket, I can always - when I'm out and about - I can make an input on my smartphone and it's just so convenient.* [P8]

To a lesser extent, the step counter within the exercise section was used.

Use of Features

Not all features of the app were used by participants. Participants did not regularly use the symptoms, documents, medication list, and calendar sections, but many saw potential advantages in using these additional features stating, "I didn't use everything but I can see other people could find it very useful" (P1). For example, due to the high frequency of medication changes in patients with heart failure, keeping an updated medication list was perceived as a positive feature. Participants did not use these features during the usability study stating that they "didn't really get a chance to go through it" (P6), and "ah, I had a look but I didn't use any of it functionally" (P7).

Table 1. Mobile Application Rating Scale subscale scores.

Subscale[a] and item	Mean (SD)
Engagement	
Entertainment	3.33 (1.03)
Interest	3.83 (0.75)
Customization	3.00 (0.89)
Interactivity	3.00 (0.89)
Target group	3.67 (0.82)
Subscale mean	3.37 (0.69)
Functionality	
Performance	2.67 (1.63)
Ease of use	3.67 (0.52)
Navigation	3.67 (1.03)
Gestural design	3.33 (0.82)
Subscale mean	3.33 (0.66)
Esthetics	
Layout	4.17 (0.75)
Graphics	3.67 (1.03)
Visual appeal	3.67 (0.82)
Subscale mean	3.83 (0.81)
Information[b]	
Quality of information	3.80 (0.84)
Quantity of information	3.60 (1.52)
Visual information	4.17 (0.41)
Subscale mean	3.78 (0.81)
Overall quality	3.53 (0.63)
Subjective score	
Recommendation	3.50 (1.22)
Use in 12 months	4.67 (0.82)
Pay for the app	1.67 (1.03)
Star rating	3.33 (0.82)
Subscale mean	3.29 (0.70)
App-specific items	
Awareness	3.17 (1.17)
Knowledge	2.67 (0.52)
Attitudes	2.33 (0.82)
Intention to change	2.33 (0.82)
Help seeking	2.33 (0.82)
Behavior change	2.33 (0.82)
Subscale mean	2.53 (0.71)

[a]Mobile Application Rating Scale values range from 1=inadequate to 5=excellent.

[b]The information quality score excluded items 13, 14, 18, and 19 from the Mobile Application Rating Scale.

Textbox 1. Summary of the themes and subthemes from participant interviews.

- App use
  - Weight, fluid restriction, and step counter
  - Use of features
  - Graphs as visual representation of patient data
- Capacity for self-management
  - Established understanding of heart failure and self-management practices
  - App for daily management of illness
  - App as communication tool
- Technical considerations
  - Attitudes toward technology
  - Functionality
  - Data entry
  - Suggested changes

Participants did not watch the instructional exercises videos due to disinterest, personal preference to undertake their own form of exercise, and awareness that they would not continue after a few weeks of watching the same videos. Additional reasons for not using all the features of the app included technical issues and a lack of perceived value for the time required for data entry. One participant commented on why he did not take the time to enter his medications and doctor's contact details into the app:

> *I'm just trying to wait until I get my medications stabilised before I make the inputs...My doctor's names and all of that information I haven't put that in yet but I will over time. It's just – ah – I've I tell you I've been so busy since getting back [home after hospital], just busy busy busy and relaxing after 4 weeks in the hospital.* [P8]

Heart failure information was considered useful for a few patients; however, most participants felt the information was already known to them; one said, "there's no new material for me actually" (P6). Another participant explained how the lack of new information relates to perceived utility of the app:

> *For me it's things I already know...I know I'm big on diet, big on health, so a lot of this information in the app I already know but it just reinforces it...I do enjoy the app but I don't need it.* [P8]

Graphs as a Visual Representation of Patient Data

Visual representation of patient data through graphs was a positive feature of the app, specifically for self-awareness. For daily weight management, graphs were deemed useful, accurate, and relevant and provided feedback to users, as viewing 7-day weight trends heightened self-awareness. A participant explained how the weight trend allowed him to be more "weight aware" (P2), and another appreciated the visual representation of health data specifically:

> *In a graphical sense you see [the weight trend] straight away. And your brain functions on that rather than on just a list of numbers.* [P7]

Self-awareness regarding mobility was deemed beneficial in the exercise section as well. The 7-day step counter graph provided an accurate picture of the mobility status to patients who used the feature:

> *I'm just trying to keep track of how much activity I'm doing, to make sure I'm…keeping moving.* [P1]

Graphical representation of patient data provided learning opportunities. Monitoring the link between fluid intake and fluid congestion can be challenging. However, graphing these data may assist to review previous day's fluid intake and to cross reference this information with fluid congestion symptoms, which may be caused by previous days' nonadherence:

> *[It] appears in your record that you can go back and look and then gives you some sort of positive understanding about what you might have done wrong...your ankles swell up the following morning and you think "ahhhh dopey bugger, I should have bloody been more careful" so and they're lessons we all learn...recognising [I've] gone over [my fluid restriction].* [P7]

Theme 2: Capacity for Self-Management

Participants were unsure how *Care4myHeart* would fit into the way they currently *understand* heart failure and conduct self-management, as using the app for heart failure would require a fundamental change in routine. However, there was potential benefit to heart failure self-management for *daily management of illness* with the benefits of accurately recording and reviewing personal health data, and as a *communication tool* for doctors to assist with care planning, as all medical information is in available one place. These three subthemes are discussed below.

Established Understanding of Heart Failure and Self-Management Practices

Participants found their own way to self-manage their health. Living with the condition for many years, understanding the importance of self-management, and setting goals regarding self-management had contributed to their existing behaviors embedded into daily life. There were many existing self-management strategies: use of a measuring jug on the kitchen bench for fluid intake monitoring, digital calendars, shared household calendar on the back of the pantry door for medical appointments/reminders, liaising with specialist nurses via email, and paper files containing medical documentation.

Participants reported satisfaction with their current health care. Notably, patients reported easy access to health care professionals for regular follow-up, ongoing education/information, and question answering. Participants spoke highly of their current general practitioner, cardiologist, and heart failure nurses:

> *I've got the heart nurse's phone number and mobile number too. She's absolutely fantastic.* [P3]

Participants were aware of and followed a self-management care plan in conjunction with their health care team, knowing their condition is life-limiting. Satisfaction with these current routines was demonstrated:

> *I mean why do I need an app to tell me that ah "do this, do this and this, and you're going to have a better life"? Whereas I get all of this so-called experts, the doctors and all of the information they give you, they tell you the same thing [as the app]...I don't necessarily need an app. Personally, I'm going to do the right thing because I want to live...I know I'm dying. I'm dying as we speak, there's no secrets here but I want to live so I'm going to do the right things.* [P8]

Existing self-management strategies were in a different location or format from the app. Participants compared the convenience of their existing strategies to using the app for self-management. Particularly, participants critiqued the need to "go to various pages on the program" (P3) to view health data, as participants commonly documented information in a notebook or electronic spreadsheet. These existing records have been tailored to the specific requirements considered important by the patients themselves or their health care team. The benefit of these existing daily records was the ability to view their health status at a glance and as a self-management checklist:

> *I can just look at one page and get the whole picture of what's happening...it's all on one page, so I can tick something when I've taken it...I just have a look at [the page] and see that I've done everything that day and basically...well that's the day done, I'm complete.* [P3]

Further, existing strategies were considered easy and time efficient in everyday life, as one participant explained about maintaining his fluid restriction throughout the day using other strategies compared with using the app:

> *I would personally keep going the way I'm going cos of the ease of doing it...[T]he easy things I'd rather just do easy, like the water in the jug...where the app's stuck in my bedroom most of the time. I've gotta go and turn it on, I've gotta go bang, bang, bang, and by the time I've sorta done the water in the jug I've well and truly finished before probably I've even get into the program properly.* [P3]

Although the app may assist in monitoring specific self-management activities like weight or fluid intake, it did not seem to embody the complexity of self-management of heart failure. Participants communicated a good understanding of heart failure (with the exception of one participant who was not familiar with the term "dry weight"). They correctly understood that fluid congestion was variable, fluid intake and diuretic medications are directly linked to fluid status, and regular self-assessment for abdominal/ankle edema was necessary. Understanding these concepts of heart failure involved a more thorough and subjective self-assessment, which was not directly equivalent to the setting's parameters within the design of the app. One participant explained his thought process while conducting a self-assessment, which was a more complex process than simply adhering to a daily fluid restriction:

> *Sometimes I will go over my fluid intake which is 1.2 [litres], sometimes I go over because I'm looking at the way I feel...I'm doing a couple of things. I'm looking at the fluid intake but I'm also looking at my body or seeing the way I feel...I'm looking at how dry I am…I'll just drink a little bit more and not get a doctor review [because] I haven't started to pick up any signs of oedema.* [P8]

App for Daily Management of Illness

The app provided a routine to manage health data like weight. Participants explained that "it generates a discipline to maintain the information" (P2) specifically regarding "the daily management of my fluid balance, it takes a lot of adjustment...to get the balance right" (P1). Entering weight was quicker using the app than the usual format of documenting weight for some proclaiming "this is a quicker way of doing it, like most computers it can store information well" (P2).

Recording health information within the app on a daily basis was considered more accurate than manual measures or memory. One participant explained how he normally relies on memory:

> *I don't record it as such but I check it every couple of days keeping a mental note – I just want to make sure there are no big variations from day to day so that's all I look for [but with the app] it's nice to have that trend, I like it, it gives you a more accurate picture.* [P6]

The health data repository and feedback within the app provided an opportunity to view a person's health status more objectively. For example, accurate recording of health data might help family members seek care appropriately during times of worsening heart failure:

> *If you go into denial stage and don't pay attention to the weight because you don't want to go into hospital*

> *or something, now they can look and see "Ah well that's not right – we should get you to the doctor" so I think it would help.* [P1]

App as Communication Tool

The app was considered a potential tool to communicate with doctors and other health professionals about assisting with care planning. Participants explained how the app could facilitate accurate information sharing:

> *[The app]enables you to communicate with your medical practitioner in a fairly accurate - one would hope - way, about what's been going on and therefore one would hope, if you were the medical practitioner, I suppose it would cause the medical practitioner a better basis of making decisions about your medical care.* [P2]

As a potential communication tool, the app could assist doctors with patient assessment. Participants frequently spoke of the potential to show doctors the graphs representing health-related trends of recent days in a consultation, as "it's quick" (P7), or over the phone, as "If you had it on a phone you could just say [to the doctor] 'Look, I'll send this through to you"' (P7). Another participant agreed with this potential:

> *The concept is good because you can take your tablet along to your doctor and he says "well how have you been?" and you can say "well there you are, there's my weight, there's my blood pressure," so you've got that information available.* [P2]

Having medical information in one place was deemed useful if all relevant data were stored in the app. Digital storage of personal medical records was considered "very powerful and very useful" (P7), as participants saw benefit in having "everything in one place" (P6) and "recorded accurately" (P1). Digital copies of medical information were considered "much easier rather than carrying an actual physical document. Sometimes I forget to take it" (P6). The potential to use the app as a communication tool was deemed especially valuable for new or temporary doctors and during medical emergencies:

> *Just air drop [my current medication list] from your phone to the doctor in casualty or whatever I think's a great, very good idea...I think that would be helpful for a lot of people especially if you come into hospital somewhere hypoxic...unconscious or whatever...or too breathless to talk about it. I've got a very very extensive list of drugs that I'm on, I think it's 35 tablets a day usually, so having that list when I've gotta provide it, makes it much easier.* [P1]

However, no participants reported using the app with members in their health care team during the time of the study. Further, the version used for the usability study was not set up for third-party access.

Theme 3: Technical Considerations

There were technical considerations influencing the experience of using the app, including *attitudes toward technology* and *functionality* and *data entry* issues. These subthemes are reported in the following section alongside the final subtheme—numerous *suggested changes* —to improve the app's design.

Attitudes Toward Technology

Predominantly, participants were not regular users of smart devices for apps or health. Three sample quotes demonstrated minimal interest in using smart devices overall:

> *I'm not a big user of phones, especially mobile phones.* [P8]

> *I don't particularly like turning computers on anyhow, I mean I'd go a fortnight without reading my emails.* [P3]

> *I'm a dinosaur and not used to using texting.* [P7]

Trust was one reason a participant would not use internet banking or purchase products using a credit card (P3). Participants reported using their smart devices for Google calendar, checking the weather forecast, playing games (CandyCrush, solitaire, or crosswords), and internet searches, and only a few used emails. In relation to technology use for health, one participant reported using a health app for self-management of heart failure and another stored his current medication list in the notes section of his smartphone. No participants reported storing medical documents electronically.

Participants believed in the inevitable advancement of technology in the contemporary era, and this was perceived to include the acceptance of health apps like *Care4myHeart* for younger generations. With the everyday use of smartphones, the younger generation "would approach it completely differently" (P7). Another participant explained:

> *I think for really the next generation and computer nerds at the moment you're on a winner there, I really do...As you get the younger ones come through you'll be fine, which will happen just over time.* [P3]

Attitudes toward technology by family members appeared consistent with those of the participants. There were no reports of receiving assistance from family members by using the app:

> *[My wife is] less techno-cradic [sic] than I am. I mean she went from a phone with a touchscreen back to a phone with push buttons on it, that's what she likes.* [P7]

The personal nature of smartphones may impact the divide between family members:

> *[It is] my phone so she didn't really take a closer look.* [P8]

Functionality

Technical challenges were reported to affect usage, which was more prevalent in Android than iOS devices. Issues with downloading the version update on Android caused one participant to discontinue participation in the study. A second participant was unable to download the updated Android version but managed to continue with the original version downloaded at the beginning of the usability study:

> *The whole thing stands still. Still. Still doing nothing...The process of downloading the app is pretty*

> *clearly signposted, I'm not complaining about that, it just didn't work.* [P2]

Technical issues with the Android version also included: lengthy app loading; a blank 7-day weight graph; and the inability to record blood pressure readings, set medication reminders, and use the clock function. Virus-protection interference due to the app being from an unknown source was also reported, regardless of approval of unknown sources in the settings section of the device. The iOS version had less technical issue reports overall but a lengthier multistep initial download process and intermittent screen freezes.

Technical issues were a barrier for ongoing use. Participants commented on the ongoing struggles with the usability:

> *I've persevered with it...but I found I was battling [with the app].* [P7]

> *Whether it's me or whether it's the program or a combination of both I don't know, but that's your problem.* [P3]

The potential benefit of the app versus the technical challenges associated with the app was also reflected:

> *I still think the idea is good and I think it's easy enough to use if it works but I've still got problems with the execution, you know.* [P2]

Interestingly, participants seldom reported technical challenges encountered by the research team during the usability study but raised these issues during the interview.

Data Entry

Navigation and data entry were specifically problematic. Participants reported physical limitations during the operation of the app, saying they have "big clumsy fingers" and their "hands shake a little bit" (P7). Participants experienced time-consuming data entry in the medications section, challenges with using some buttons, and confusion completing or updating the settings.

Strategies to overcome these limitations were evident, as participants had insight into their own ailments:

> *Sometimes I lick the end of my fingers and that might be a factor of fluid, my fluids are very low and I'm quite dry.* [P7]

Awareness of these functional limitations was a factor in participants choosing a tablet device over a smartphone if they owned both: "I've got fat fingers and the phone's got a small keyboard" (P2). Further, the consequences of incorrect data entry in the settings component of the app caused inappropriate alerts. One participant explained an alert associated with incorrect entry of dry weight:

> *It told me horror stories about what I should do in terms of consulting my medical practitioners, when in fact I had simply a [settings] error on the machine.* [P2]

Suggested Changes

Many suggested changes were provided in relation to data entry issues, utility by the heart failure population, and making it more appealing for the user.

There were many usability improvements regarding the data entry challenges experienced. Participants wanted more control over their data: "people are generally pretty honest about the way they deal with their own data" (P7). Participants wanted to clear previously entered or incorrect data, edit previously entered data, and enter retrospective data in case it was missed, causing incomplete weight graphs:

> *If you're out for the day say and you leave your phone at home and you come back and want to add the data the following day, you can't do it, so I think that is definitely a negative.* [P7]

Having an empty data entry screen without predicted or previous amounts was important to avoid confusion during data entries. This was noted for documenting fluid intake and entering daily weight:

> *It comes up with the last weight you put in so you have to delete that before you can actually [put] a revised weight in and I think that's a mistake. I think the window should be clear and you just enter in the data you want to enter.* [P7]

In addition, there were suggestions to improve the applicability to the patient group. These included recording more health data, documenting medication variations more easily, adding a medication checklist function, going over the maximum fluid restriction volume, and adding a free-text general notes page.

Making the user interface more appealing was deemed necessary for engagement with the app. Suggestions included visualization of fluid overflowing out of the fluid jug or turning red in color and more graphical information with an increase to a 14-day trend. Participants explained their wish for a more interesting interface:

> *If you can have some whistles and bells and things like that–it just makes it a little bit more interesting.* [P8]

> *Some screens are very average looking...I think if you could brush it up a little bit and um, make it more appealing some of the screens...would be nice actually.* [P6]

These improvement suggestions would perceivably improve the utility of the app:

> *[To] make notes about day to day things…just like a general notes page. That would be a great idea...That would be the decider for me to use it over the other one [app].* [P1]

Miscellaneous suggested changes included a simpler keyboard, ability to change to horizontal view on the tablet version, and appearance of the logo on more screens.

Discussion

Learning from Failure

This paper presents findings from a usability study conducted with patients using an mHealth app for heart failure. We explored the way the app was used and its perceived impact on self-management of disease. In this context, frequently used features were weight and fluid restriction tracking, and graphical representation of data was particularly beneficial. Using technology for self-management would fundamentally differ from current practices; however, use of the app was correlated with the potential utility for daily condition management and as a communication tool. The overall app quality score, as assessed by the MARS, was slightly higher for *Care4myHeart* (3.53) than an average of the 34 comparable heart failure-support apps on the consumer app stores (3.4) [12]. In its current form, the perceived impact on health behavior change was classified as "poor" in the MARS app-specific subscale. Patient experiences of using various app components highlighted challenges and opportunities for design improvements for the next version of the *Care4myHeart* app. In addition, patient experiences have implications for researchers investigating digital health systems for chronic disease and consumer app designers wishing to incorporate human factors. Many lessons were learned from the usability study and are described below.

Lessons Learned

The following lessons were learned from the evaluation of *Care4myHeart* by patient participants.

Lesson 1: If Technology Is Not Integrated Into Everyday Life, It Is a Significant Barrier to Adoption

Integrating self-management with normal life patterns has been identified as a key enabler of effective self-care in heart failure [20], and participants in this study have well-established daily routines. Clarke et al [20] described how patients with heart failure enlist "cues" in everyday life as routines to facilitate guideline adherence. For example, to integrate self-management activities with the morning routine, patients may place pill boxes on the breakfast table as a visual reminder for medication adherence [20]. Participants in the usability study for *Care4myHeart* reported various cues and, except for a few, reported their ease and desire to continue with the existing routines. Demonstrating this, the use of a measuring jug on the kitchen bench for daily fluid restriction management served three functions: a visual reminder to limit oral fluids, a functional measuring tool, and an accurate visual representation of cumulative fluid intake at any point in the day. This presents a more convenient option for participants whose smart devices were located elsewhere in the house and had a more practical option, given the inability of the technology to measure fluid volumes. Participant reflections in comparing the use of technology in heart failure were consistent with the recent study conducted with older people with heart failure: Nguyen et al [9] found that "Some patients did not find technology to be useful or relevant in their daily activities because they were already comfortable with their routines." Similar reasons likely contributed to the low perceived impact of the app on health behavior change reported in the MARS and indifference to explore all app features, as participants felt the app did not enhance existing self-management. Consequently, introducing the app at the commencement of a self-management regimen may be more beneficial and needs further investigation.

The private nature of smart devices may be a barrier to adoption itself. In this study, no participants reported the involvement of family caregivers regarding the use of the *Care4myHeart* app. Yet, historically, caregivers are frequently involved in heart failure [21] with some patients dependent on their caregivers to make health-related decisions [9]. The gradation of dependency of caregivers for older adults with chronic conditions [22] presents challenges in designing future support interventions [20] when daily health-related activities involve caregivers. The technology risks excluding caregivers unless the design supports their active involvement and the resulting design presents a perceived benefit to the patient *and* caregiver.

Lesson 2: The Biggest Benefit Is the Opportunity for Improved Self-Awareness and Continuous Learning in Heart Failure Management

The timely detection and recognition of and action to subtle changes in symptoms was noted as a key skill for effective self-management of heart failure [20]. According to patient experiences, the self-management app we developed offered possibilities for a more active role in daily recording and reviewing of heart failure-related data. Participants specifically observed a benefit in the graphical representation of their data with the ability to view trends, detect changes representative of worsening heart failure, and take action accordingly. Previous studies have shown that skills in managing heart failure evolve over time and learning from past experiences are helpful in applying effective strategies to daily life [21]. This was particularly evident with patients' experiences using the 7-day weight trend feature. Participants felt it was accurate and timely and provided an objective representation of their health status to watch or act when needed. We believe that the use of mHealth via an app with real-time representation of data trends would strengthen patient empowerment and decision making in self-management.

However, to realize the potential for improved self-awareness and continuous learning, engagement improvements are needed. A recent review, which compared the quality of 34 heart failure support apps on the consumer app stores using the MARS, found the lowest score was for the engagement subscale (2.9/5.0) [12]. This led to a call for further improvements in engagement of mHealth apps for heart failure support. In the context of our study, *Care4myHeart* had an engagement subscale mean of 3.37, which was higher than the average in the review. However, this score still falls short of the "good" range. In this regard, participants conveyed valuable suggestions to improve the interactivity and customization of the app, in addition to suggestions to make the interface more interesting and entertaining. Incorporating the many suggestions provided from (just) six participants in the study may greatly improve the interface for future users. The suggested changes are relatively minor to incorporate in iterations, as they have been in other usability studies [23] achieved through usability studies of similar sample sizes of 5-10 participants [24-26].

Lesson 3: Patients Need a Way to Manage Their Health Information Across the Health Care System

The findings of this research indicate that participants want effective ways to share their data with health care professionals for ongoing care. Participants perceived the app to be effective as a communication tool to share their data in a timely, accurate, and visual manner, so that health care professionals can be armed with all relevant health information contained in one system, especially in an emergency or unfamiliar health care setting, for care planning. Australia is transitioning to an opt-out electronic health record; however, during the usability study period, participants' health information was largely held in silos by individual health providers. Participants reported the safety and quality benefits to record, store, and manage health information in one place, whether it was the *Care4myHeart* app or another assistive technology. These participants' perspectives are mirrored in a recent study investigating experiences using the patient-accessible electronic health record used in Sweden [27]. Over 96% of survey responders had an overall positive perception of the system, reporting the following highest-rated reasons why they felt it important to have access to their health-related information: (1) it makes patients feel informed, (2) it improves communication between medical staff and the patient, (3) it improves the understanding of the patient's condition, and (4) it makes patients feel safe [27].

Condition-specific mHealth apps have limitations for integration to current health information systems across acute care, primary care, and community care. Standalone apps will not reach their potential to aid self-management without integration across health care providers, because, like other chronic conditions, patients with heart failure have concurrent comorbid conditions [1], experience frequent hospitalizations [3], and require a team approach across health care sectors [5]. There is increasing recognition that health services for those living with chronic conditions need to be more integrated, coordinated, and patient focused across the continuum of care [2]; however, mHealth has specific challenges in addition to other service redesign efforts. For example, health system readiness, organizational resistance to change, policy uncertainties, and unclear reimbursement schedules for clinicians have been previously identified as barriers to the successful implementation of mHealth technologies for chronic conditions [22].

Lesson 4: Technical Challenges are a Significant Barrier to Use With Most Patients Unlikely to Persevere

Attitudes toward technology use impacted participants' experiences of using the app. The complex components within the app requiring more navigation and data entry, for example, the medication list feature, were infrequently used. These complex components were more likely to have technical and functional issues, which was an additional deterrent reported by participants with less confidence of using technology. For the few participants who self-reported daily app use, the technical challenges were less of a hindrance, but these participants were more likely to provide specific interface-improvement suggestions.

The findings of this usability study have led to recommendations regarding technology use for usability studies conducted with patients, which may be particularly beneficial to clinician researchers. First, testing and re-testing before allowing patients to use the technology is important to help mitigate frustration of poorly functioning technology, a previously reported fear in older adults with heart failure [9]. Second, avoiding version updates during a usability trial will limit confusion, particularly when the researcher cannot screen share with patients located in rural areas to guide the process. Finally, consider recruiting patients who use apps daily as "early adopters" of mHealth for heart failure because of the variable levels of technology acceptance in this patient population [9]. Our findings were consistent with those of Nguyen and colleagues [9] who found that patients were keen to manage their heart failure and willing to uptake self-management recommendations, but discovered that for some patients, adopting a new technology on top of their daily health routines may be of little benefit. Time and effort were barriers to technology acceptance [9], consistent with the findings from this study, where the ease and convenience of continuing with existing self-care regimens outweighed the technical challenges of learning how to use a new app. This would also account for the seldom reporting of technical difficulties during the study. Participants likely made decisions about their acceptance of the app early in the study period and therefore lacked motivation to troubleshoot technical issues with the research team. We found these barriers to technology use regardless of the participant's keen interest to participate in the research and optimism for technology to assist with their health, noting that the demographic of study participants were older men only.

We tried to minimize technical challenges by using a participatory, co-design approach involving patients in each stage of the development; however, this was not reflected in the study's findings. This challenges the assumptions of the co-design methodology in addressing the needs of target users and improving usability and places further emphasis on the nonhomogenous attitudes of patients with heart failure when considering technology and health.

Recommendations for Future Research

Future research should explore in what formats and contexts technology can positively complement daily self-management activities conducted by patients with heart failure. Importantly, we must incorporate the vital caregiver role in the design of condition-specific mHealth because of their active role in self-management support in the home environment. A more focused understanding of the design considerations to engage users in an interesting and beneficial way is likely necessary for adoption and ongoing use, which will require interdisciplinary collaboration between designers, developers, health care providers, and health care consumers. Third-party access to medical information in the app, especially in an emergency, may be an important design recommendation and should be investigated.

With the limited number of evidence-based mHealth interventions moving past the pilot or feasibility stage [22], future studies should investigate the many barriers to adoption and sustainability. Implementation science of mHealth apps for self-management of chronic conditions as an adjunct to existing

care is an important area for further research, specifically for investigating perspectives of clinicians, health system administrators, and policy makers.

Limitations

Since data collection, the authors are aware of a user version of the MARS called uMARS [28], which would have suited this participant sample more specifically as health care consumers. A limitation of this research is the selection bias of the patients. First, as per the inclusion criteria, all participants owned a smart device. Second, less adherent patients, for whom the app may be most beneficial, are often not willing to participate and may have reported different experiences from this sample. The findings from this study conducted with a small and homogenous sample cannot be generalized to the wider heart failure population; nevertheless, they provide insight for further research on the topic.

Conclusion

A mixed-methods evaluation of patient experiences using an mHealth app for heart failure showed how the app was used and its perceived impact on self-management. Daily self-management habits are established without the use of technology, so patients were unsure how the app would fit in their routines. Nevertheless, participants saw the potential of the app to aid daily condition management, particularly regarding weight and fluid restriction management, and serve as a communication tool for health care professionals involved in their care.

Understanding users' experiences contributes to design improvements for the *Care4myHeart* app, and the lessons learned have implications for researchers and development teams to advance the quality of consumer mHealth apps for chronic conditions. Future studies should investigate the barriers to adoption and sustainability of consumer mHealth interventions, including whether introducing such apps is more beneficial at the commencement of a self-management regimen. Research into how to incorporate the important role of caregivers in the design of technology to support self-management in the home environment is also needed.

Acknowledgments

We are thankful to the patients for their contributions to this research. The research reported in this paper is supported by a St Vincent's Clinic Foundation grant and an Elite Research Scholarship provided by The District Nurses, Hobart, Australia.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Modified Mobile Application Rating Scale.

[PDF File (Adobe PDF File), 107KB - humanfactors_v6i2e13009_app1.pdf]

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Abbreviations

mHealth: mobile health
MARS: Mobile Application Rating Scale

Edited by A Kushniruk; submitted 03.12.18; peer-reviewed by S Donnelly, M Cajita; comments to author 22.01.19; revised version received 04.03.19; accepted 21.03.19; published 20.04.19

Please cite as:
Woods LS, Duff J, Roehrer E, Walker K, Cummings E
Patients' Experiences of Using a Consumer mHealth App for Self-Management of Heart Failure: Mixed-Methods Study
JMIR Hum Factors 2019;6(2):e13009
URL: http://humanfactors.jmir.org/2019/2/e13009/
doi:10.2196/13009
PMID:

6.5 Chapter 6 summation

Chapter 6 reported the final design of the *Care4myHeart* app and the usability study conducted with patients with heart failure who were not involved in the co-design phase. The chapter addressed Research Objective 3: To understand the patient experiencing using the app for heart failure self-management.

Despite the user involvement in the design, patient experiences of using this app were not overwhelmingly positive. The Design Science Research framework used for the design aimed to facilitate the development of an intervention to support heart failure self-management which was relevant to stakeholders and consistent with the evidence-base. The final design, including the features and functions of the *Care4myHeart* app, was presented in Publication 7 with the rationale from operationalising the framework in practice. However, the usability study uncovered that when the app was tested with a new subset of patients, participants were unsure how it would fit into existing self-management routines. Technology was not integrated into their daily life, and although patients saw potential benefits for the app to aid daily management of their illness and act as a communication tool, these patients did not see an additional benefit to their established health routines.

Design limitations, highlighted in Publication 7, were evidenced in the findings from Publication 8. Two main limitations were identified. First, the design outcomes were limited by stakeholders involved in the research and second, context-specificity restricts the portability of the design. These limitations may have impacted the perceived unlikely impact on self-management behaviour change revealed in Publication 8. As they were a different subset of patients with heart failure, it is possible that the needs of patients involved in Phase I and II varied considerably from the needs of those involved in Phase III. Another explanation is recruitment bias as patients who self-selected to participate in Phase III may have had more confidence in the daily management of their condition. Subsequently, patients may not feel the need to improve their self-management making the proposed app redundant.

Insights from this chapter highlighted barriers to technology adoption for patients who have established self-management routines. Importantly, Phase III uncovered uncertainty around the co-design methodology in addressing the needs of target users. For example, the patient personas developed for this research did not reflect a patient with established self-management routines, nor confidence in using mobile technologies. In summary, a strength of the design was the incorporation of local stakeholders, yet a new sample of local patients do not see added benefit to using the app

for self-management. Therefore, patients with heart failure, and those who chose to participate in this research, are nonhomogeneous. The discussion and conclusion chapter (Chapter 8) further explores the implications of the findings from Chapter 6 in the context of the whole research. Next, Chapter 7 reveals the findings from Phase IV where the experience of co-design participants was explored.

Chapter 7 : Phase IV – Process evaluation

Understanding the experience of stakeholders involved in the co-design process is the focus of Chapter 7. The chapter reports Phase IV which involved a process evaluation and addresses Research Objective 4: To evaluate the multi-stakeholder co-design process.

Figure 19 demonstrates that Phase IV involved an evaluation the empathise, define, ideate and prototype Design Thinking stages, also referred to as Phase I and II. As the 'test' Design Thinking stage involved patients not involved in the co-design process in the usability study conducted in Phase III, it was omitted from this process evaluation.

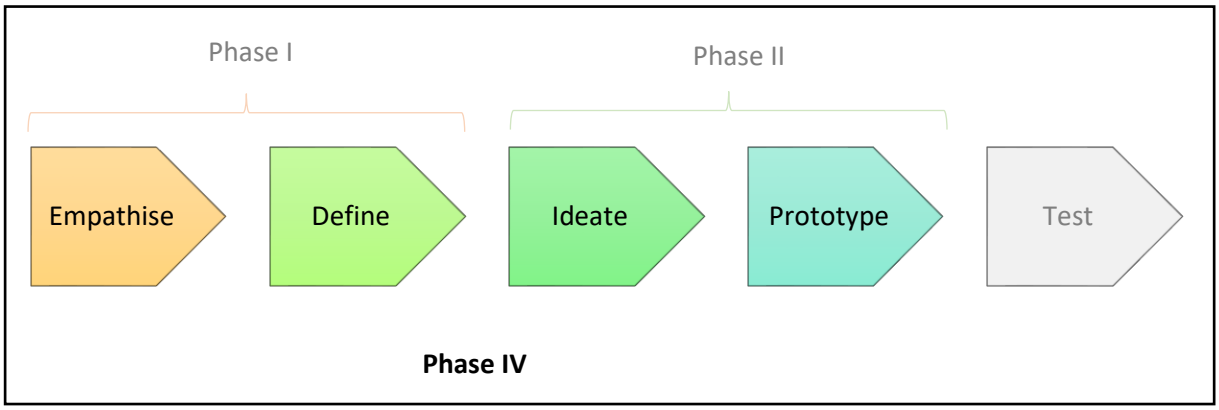

FIGURE 19. PHASE IV IS AN EVALUATION OF THE EMPATHISE, DEFINE, IDEATE AND PROTOTYPE STAGES OF THE DESIGN THINKING PROCESS

Chapter 7 reports the final research phase. The main findings and challenges from operationalising co-design in the hospital setting is presented, based on real accounts from various stakeholders. Understanding experiences and perspectives of those involved can help shape future co-design project plans to better leverage the skills and expertise available in the clinical setting.

Chapter 7 is divided into the following sections:

Section 7.1 is the preface to Publication 9 which reports the findings from interviews conducted with the participants involved in the co-design process within the hospital setting;

Section 7.2 presents Publication 9 - *Co-Design of a Mobile Health App for Heart Failure: Perspectives from the Team* accepted for publication with Studies in Health Technology and Informatics, due to be published in August 2019; and

Section 7.3 provides a summation on Chapter 7 and how it addresses Research Objective 4.

7.1 Preface to Publication 9

The final publication in this thesis reports the final research phase (Phase IV). Publication 9 reports interview findings conducted with participants involved in the co-design process from Phases I and II. To further understand how co-design is conducted in practice, specific aims were to gather stakeholder perspectives on the co-design process and the design outcome itself.

Rigorous studies on the implementation and impact of co-design in the healthcare sector are lacking (Dawda & Knight, 2018; Donetto et al., 2015). Specific gaps include selecting a suitable stakeholder group and ways to interact with stakeholders to benefit the design. The contribution of Publication 9 to the knowledge-base is through examination of stakeholder perspectives of the co-design process, clearly reported as successes and failures. Understanding stakeholder perspectives on co-design activities, motivations for participation and opinions of the design outcomes may assist other clinician researchers embarking on a co-design process.

To assist with dissemination of the research findings from Phase IV, the open access journal the IOS Press series *Studies in Health Technology and Informatics* was selected for this manuscript submission. The manuscript has been peer-reviewed and accepted for publication and will be presented at the 27th Australian National Health Informatics Conference (HIC 2019) to be held in Melbourne, Australia on 12-14th August, 2019. It will be published online via open access through IOS Press.

The incomplete citation for Publication 9 which is in press, is as follows:

> Studies in Health Technology and Informatics, Woods, L., Roehrer, E., Duff, J., Walker, K., & Cummings, E., Co-Design of a Mobile Health App for Heart Failure: Perspectives from the Team. (In press, IOS Press).

7.2 Publication 9: Co-Design of a Mobile Health App for Heart Failure: Perspectives from the Team.

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Co-Design of a Mobile Health App for Heart Failure: Perspectives from the Team.

Leanna WOODS[a,b,1], Erin ROEHRER[a], Jed DUFF[c], Kim WALKER[a] and Elizabeth CUMMINGS[a]
[a] *University of Tasmania, Australia*
[b] *St Vincent's Private Hospital Sydney, Australia*
[c] *University of Newcastle, Australia*

Abstract. Using a Design Thinking and co-design methodology, hospital staff and consumers developed a novel mobile health app for heart failure self-management. Various stakeholders engaged in three development stages: interviews, design workshops and prototype iterations. Eleven of 18 co-design team members reflected on the co-design process and design outcomes. A total of 144 data points were collected: 96 about the co-design process and 48 about the design outcomes. Successes and failures reflect the strengths and weaknesses of operationalising co-design in practice. Overall, participants were surprised the design outcomes were achieved. The app was considered a supportive tool for meaningful self-monitoring and patients believed the app would be applicable to their situations. Our findings suggest that local co-design can be achieved through meaningful partnerships, and managing stakeholders was key to the project's success.

Keywords. Co-design, patient engagement, participatory design, heart failure, digital health, mobile app, evaluation

1. Introduction

In healthcare, co-design refers to the partnership of consumers, carers, families and health workers to improve health services [1]. It challenges the traditional approach to healthcare improvement where patients are only passively involved [2], if at all [3]. Co-design presents an opportunity to realise the potential of the biggest resource providers have to improve care, the patients themselves [2].

Co-design processes can be powerful but also challenging [3]. For patients, resultant healthcare services are perceivably more humane and person-centred [4], contributing to greater satisfaction in care [1]. For healthcare organisations, co-design can facilitate idea generation, tangible service changes and improvements in the day-to-day experience of giving care [1]. However, in clinical environments where co-design could be advantageous, there may be no formal, practical or financial support for its initiation and execution [4]. Practical challenges include patient and caregiver recruitment or retention, and lack of support, resources or managerial authority [4].

An increasing number of healthcare environments are engaging with co-design worldwide [1] but rigorous studies on its implementation and impact are lacking [1, 3] particularly in acute healthcare settings [4]. In understanding how to better operationalise

[1] Corresponding Author: Leanna Woods: Email: leannaj@utas.edu.au

co-design in practice, analysing stakeholders' accounts of co-design processes are needed. In this research, we evaluated the co-design processes enlisted to develop a mobile health application (app) to support patient heart failure self-management. This paper reports the experiences of clinicians, patients and family caregivers engaged in the co-design process and their perspectives on the design outcomes.

Co-design activities required formation of a multi-stakeholder team with the shared goal to design and develop an intervention for heart failure self-management. The co-design team undertook a Design Thinking process of innovation [5]. The development took nine months and was led by a clinician researcher embedded in the health service as a cardiac clinical nurse specialist. While the specific app development processes are reported elsewhere [6-8], stakeholders were involved in three stages of development: interviews, workshops and iterations. These development stages are detailed as follows:

1. To capture experience data and gather stakeholder needs, interviews were conducted with patients, family caregivers and clinicians. Interview content was analysed and creatively represented in posters (journey map, stakeholder map and patient personas) and design brief summarising design priorities.
2. Then, two 2-hour multi-stakeholder design workshops were conducted on the hospital campus. Design sprint activities (lightning demos, idea matrix, greatest hits and solution sketch) resulted in a storyboard of the app on a whiteboard.
3. Lastly, clickable prototypes were developed and iteratively refined based on feedback sessions conducted with individual stakeholders.

2. Method

2.1. Participants

Ethical approval to conduct the research was granted from the University of Tasmania and St Vincent's Private Hospital Sydney. The co-design team consisted of 7 multi-disciplinary hospital clinicians, 7 local patients and 4 family caregivers. Seven clinicians, 3 patients and 1 family caregiver participated in the evaluation reported in this paper.

2.2. Data collection

Participants completed an interview to gather perspectives and insights about the co-design process and reflect on the design outcome. Interviews occurred between February and May 2018 and were predominantly conducted in person on the hospital campus. Three participants responded via email exchange.

First, the 'Rose, Thorn, Bud' technique from Design Thinking [9] was used to evaluate the process. The technique is a simple, versatile method for identifying issues and insights, to then uncover emergent patterns across all respondents [9]. Participants were asked to respond to the question '*How did the app design process go?*'. The strength of the approach was initial codifying of research data as participants wrote one issue, insight or idea directly on coloured post-it notes. Red notes represented positive aspects of the co-design process, blue represented negative aspects and green represented improvement suggestions if the process was repeated [9].

Second, to gather opinions about the design outcome, participants were asked to respond to two questions by writing directly onto post-it notes. The questions were: *What do you think of the app?* and *Would you use or recommend the app?* In answering these

questions participants were encouraged to provide rationale or examples and consider the healthcare context in which the app would be implemented.

2.3. Data analysis

The research team used an affinity diagram, modified for application as a Design Thinking technique [10], to find connections in the data and identify themes. Data points (participant response on a post-it note) were reviewed collaboratively and placed alongside other, similar data points. Consistent with this methodology [10], the process was repeated until all data were clustered, then headers were created to label what connects the data within the cluster. The headers generated from this data analysis process informed the findings of the study. Headers from the co-design process data were reported as either successors or failures to reflect the strengths and weaknesses as expressed by participants. Headers from the design outcome data represented participant opinions of the app itself.

3. Results

A total of 144 data points were collected from 11 participant interviews. Clinicians included a cardiac nurse consultant, cardiologist, physiotherapist, dietitian, pharmacist and two heart failure nurse practitioners. Two male patients, a female patient and a male caregiver participated with an age range of 51-80. First, the co-design process evaluation is reported and second, the design outcome opinions are presented.

3.1. Co-design process evaluation

Ninety-six data points were collected representing 64 positive aspects, 14 negative aspects and 18 improvement suggestions. Data analysis resulted in a list of successes and failures as experienced by participants. See **table 1**.

Table 1. Successes and failures of the co-design process as reported by various stakeholders.

Success/ failure	Key finding	Stakeholders
Successes	Structured approach with regular feedback	Predominantly clinicians
	Involving many stakeholders including patients	Clinicians, patients and family
	Co-design activities that were quick, flexible and involved ongoing communication	Clinicians, patients and family
	Participation was a research engagement opportunity	Clinicians
	Participation was an opportunity to give back	Patients and family
Failures	Inadequately diverse stakeholders	Clinicians and patients
	Not reviewing comparable health apps	Clinicians and patients
	Not adequately addressing the app's implementation	Nurse practitioners only

3.1.1. Successes

The structured development approach with regular feedback, was efficient. Described by clinicians as 'organised chaos' (clinician 1), workshops were 'well organised, productive and ran to schedule' (clinician 2). Clinicians were positive about their ability to provide

regular feedback during the design and the efficiency of the process, exampled by the response '[it was a] time efficient process throughout development' (clinician 3).

Involving many stakeholders including patients was beneficial to the quality of the final design. Responses demonstrated the positive impressions of including various stakeholders from early in the design process: 'including patients in development process to get their ideas and perspectives' (clinician 4), 'incorporating key stakeholders into process from the beginning' (clinician 3), and a 'multi-focused consultation all together in the same room with all stakeholders including patient with feedback' (clinician 5).

Co-design activities that were quick, flexible and involved encouraging, ongoing communication were reflected on positively. Clinicians needed to manage their existing workload stating 'I'm too busy for a whole day [workshop]' (clinician 1). Patients and family caregivers commented on the ongoing communication during the project, for example: 'our email correspondence was informative and encouraging' and the 'project lead [had] intuition to ask the correct questions' (patient).

Participants reported their motivation to participate in the project. For clinicians, co-design was a research engagement opportunity. Clinicians communicated their professional responsibility to be 'involved in campus research' (clinician 1) and found the learning process interesting 'by participating in [the] process I also learnt about the app design process and Design Thinking tool' (clinician 2). For patients and family caregivers, participation was an opportunity to give back to the health service, as one patient described 'they're doing lots for me . . . I would do something for them'. Patients responded positively to their invitation to be involved in the co-design process in the example responses: 'glad to come in and help' and 'I feel honoured to be asked'.

3.1.2. Failures

The stakeholders involved were inadequately diverse to capture a wide variety of perspectives. Suggestions included engaging more patients to get 'a better representation of patient's view' (clinician 2), especially 'early in the design' (patient). Involving younger patients, more caregivers and a public health nurse was also recommended.

Reviewing comparable health apps may have been beneficial for the design. An 'overview of similar products' and 'other chronic disease applications' were improvement suggestions from a patient and a clinician, while the physiotherapist would have 'researched options for exercise videos' if they had anticipated the challenges associated with designing the exercise section of the app.

Both nurse practitioners responded with several unanswered questions regarding the app's implementation. These responses included: 'where to now?', 'can we use this [app]?' and 'who takes control?', listing legal, funding and health fund issues as specific barriers to implementation.

3.2. Co-design outcome opinions

Secondly, 48 data points represented team members reflections on the design outcomes. Participant responses were almost all positive with participants surprised the design outcomes were achieved. This was demonstrated by the comments: '[I'm] surprised the app came to life…all that was discussed in the focus/planning groups came true' (clinician 4) and 'congratulations to where you've got to in the development' (patient).

Ten of 11 participants interviewed would recommend or use the app. Clinicians would recommend the app for the 'younger generation' of patients and carers 'depending

on IT skills' specifically regarding their ability to use mobile technologies. Patients would use and recommend the app but recognised they would need 'a few days to be at ease with it' and it would take 'a while to get used to doing it [self-management] this way'. One clinician said they *might* recommend the app if the exercise section was reviewed and updated. None said they would not use/recommend the app.

The app was considered a supportive tool for meaningful self-monitoring for all stakeholders. Clinician 5 communicated how the app may be used 'I see it will be a wonderful tool to support heart failure patients and their family and clinicians'. Positive features were ease to 'self track', using 'meaningful, timely data' specifically through 'self-reflection of symptoms and how it ties to behaviour'. The user interface was considered simple, easy-to-use, particularly favouring the modular design with a customised home screen to address patient preferences. Generally, the information within the app was considered comprehensive, however one clinician suggested it may be 'too much' information to manage for the target patient group.

Patients believed the app would be relevant to their situations. The main reasons were the convenience of having data 'all stored together' especially for 'things I don't remember like blood pressure – it's all documented' and to mitigate using a paper diary. Clinicians believed having the data in one system would improve clinicians' time management and communication, stating the app is like an electronic health record.

4. Discussion

The in-hospital co-design process was overwhelmingly positive for those involved. Two key lessons were learned from this evaluation.

Key learning 1: Using a structured approach to innovation, local app design and development can be achieved by clinicians and patients. Participants reported success applying the Design Thinking process to the development but similar, highly-structured co-design approaches also exist. A notable approach is Experience Based Co-design [3]. A free-to-access toolkit for the Australian healthcare sector [1] and an 'accelerated' version [3] to achieve a quicker, lower cost result, are now available. Adopting the 'monitor and maintain' component of this approach [1] may have addressed the concerns around the implementation of the app. Regardless of the chosen approach, clinicians can lead co-design processes, successfully partner with consumers, and make embedded innovation and quality improvement a reality.

Key learning 2: Executing a co-design project is about stakeholder management. The format of co-design often involves a renegotiation of roles and expectations of stakeholders, particularly around power dynamics between provider and consumer [3]. The findings suggest this dynamic of stakeholder interaction resulted in positive experiences, similar to other healthcare co-design projects [2]. However, the relative lack of documented evaluations of co-design projects is likely reflective of the stage of adoption in the health sector [4] and raises recommendations for future research. Of particular significance is stakeholder selection. Our evaluation reported that 'involving many stakeholders' was a success but 'inadequately diverse stakeholders' was a failure. This signifies the importance of building meaningful, appropriately-sized co-design teams. Donetto and colleagues suggest 'as many stakeholders as possible have input' [3[p234]], however in health research - at least in this project - participation was limited by ethical approvals, access to volunteer consumers and competing priorities of clinicians and organisations. Our findings also suggest those involved in co-design are

loyal to the design outcomes and may be less likely to identify barriers to sustainability of design outcomes. Consequently, involving a new subset of patients to test the designs would be needed to capture the app's true usability for an uninitiated user.

In interpreting the findings, it is necessary to highlight the study's limitations. First, few patient and family participants were involved to the project's completion, so the findings were weighted towards clinician perspectives. Second, the clinician researcher in the co-design project conducted the interviews rather than a non-biased third party.

5. Conclusion

Analysis of stakeholders' accounts of the co-design process has enabled a deeper understanding of the strengths and weaknesses in operationalising co-design. These understandings have supported our initial impressions that co-design can be achieved with a sincere partnership between staff and consumers. However, 'inadequately diverse stakeholders' was a failure, signifying the importance of selecting a meaningful, appropriately-sized co-design team. The findings have suggested that managing stakeholders throughout the design is key to the project's success.

Acknowledgments

This project is supported by a St Vincent's Clinic Foundation Grant and the University of Tasmania's Elite Research Scholarship funded by The District Nurses.

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7.3 Chapter 7 summation

Chapter 7 presented research Phase IV and addressed Research Objective 4: To evaluate the multi-stakeholder co-design process. Participant experiences were overwhelmingly positive, both in terms of the co-design experience and perspectives on the design outcome. The evaluation process also uncovered the motivation behind participation, which provide insight into how healthcare improvement projects in a health service are carried out. To engage with staff and consumers, the benefits of participation need to outweigh the inconvenience of their attendance and is an interesting area for further study.

The methodological approach used for data collection and data analysis was a rapid and flexible evaluation method. The 'Rose, Thorn, Bud' technique, brainstorming session with post-it notes and initial codifying of data by participants themselves was productive. The application of the technique was as effective and efficient as when it was applied in Phase I to gather clinician perspectives prior to the design and development of the app. Two key strengths of the 'Rose, Thorn, Bud' technique were versatility and efficiency. First, the technique was versatile, as it was used to examine an existing service (Phase I) and as a process evaluation technique (Phase IV). Second, the method has demonstrated to be effective. For both applications of the technique, the qualitative data collected was rich and meaningful without an unnecessarily long data collection and analysis phase. Further, it can be conducted without the need for specialist research knowledge, making it accessible to a wide range of stakeholders to adopt in their practice.

Chapter 7 uncovered the strengths and weaknesses of the co-design process which have significance to other clinicians or researchers considering multi-stakeholder engagement and will be further discussed in Chapter 8.

Chapter 8 : Discussion and conclusion

Research Objectives 1-4 have been addressed in Chapters 4-7 respectively. This discussion presents a general representation of the research findings in the context of the overall research. In this chapter introduction, the study procedures are summarised, the findings are listed in table format and the structure of Chapter 8 is explained. Importantly, it is structured around the stakeholder groups involved in the research.

This nurse-led research evolved after discussions with clinicians and patients which resulted in a common goal to support patients with heart failure self-management through the development of a new mobile health app. The research question was:

Research question

How might patients be supported in heart failure self-management with a mobile health app co-designed by patients, family caregivers and clinicians?

A multi-stakeholder team of patients, family caregivers and clinicians was formed. Four research phases were conducted to address four research objectives. First, in order to explore stakeholder perspectives prior to the design and development of the app, stakeholders were interviewed and their responses visually represented in design artefacts (Phase I). Second, the design and development processes used to co-design the app with patients, family caregivers and clinicians were disclosed (Phase II). Third, to understand the patient experience of using the app, a new subset of local patients were recruited in a usability study to gather perspectives on using the app for self-management (Phase III). Finally, to evaluate the multi-stakeholder co-design process (Phase IV), interviews were conducted eliciting data on the co-design experience and the design outcome.

Consistent with the research philosophy incorporating a person-centred approach to the research, the discussion is structured around each stakeholder group. The key findings from each stakeholder group (patient and family caregiver; clinicians; and lead clinician researcher) are presented first, followed by a section on stakeholder interactions. The findings are discussed in relation to the research question and incorporate the relevant literature. Table 4. presents the key findings which emerged during the nurse-led co-design process described in this thesis.

TABLE 4. SUMMARY OF KEY FINDINGS

Stakeholder	Key findings
Patients and family caregivers	Daily self-management habits are established without the use of technology, so patients were unsure how the app would fit in their current routines.
Clinicians	Clinicians were easily recruited, highly engaged and continued participation throughout the co-design process.
Lead clinician researcher	Leading a highly structured innovation process allowed efficient development of the application.
Stakeholder interactions	Co-design methods helped negotiate tensions between stakeholders in the design.

Chapter 8 is divided into the following sections:

Section 8.1 provides a discussion on the key findings for the patient and family caregiver stakeholder group;

Section 8.2 presents a discussion regarding the key findings for clinician stakeholders as healthcare providers involved in this co-design research;

Section 8.3 involves a discussion on the key findings in conducting the research from the perspective of lead clinician researcher who is also the student, clinician and app developer who facilitated co-design with no previous design experience;

Section 8.4 presents a discussion on the key findings regarding stakeholder interactions in regard to the importance of navigating tensions to ensure the research objectives were addressed;

Section 8.5 summarises the contributions of this research. Contributions are presented at a substantive, methodological and theoretical level;

Section 8.6 indicates the implications of this research for researchers, clinicians and developers who are undertaking co-design research, mHealth development or conducting usability studies;

Section 8.7 discusses the limitations of this context-bound, experiential research whereby the role of the student researcher cannot be dismissed but the findings may be relatable to others. The section concludes with a section explaining the implications of participant self-selection on the findings of this research;

Section 8.8 indicates areas for future directions; and

Section 8.9 provides the concluding remarks as the final statements of this thesis.

8.1 Patients and family caregiver stakeholder group

Key finding

Daily self-management habits are established without the use of technology, so patients were unsure how the app would fit in their current routines.

Self-management practices were not influenced by use of the *Care4myHeart* app as perceived heart failure related behaviour change was rated by participants as 'poor'. If we are to make positive change in practice by producing an intervention which has impact, then this is the most significant research finding resulting from this research and is discussed below.

Few heart failure interventions have incorporated an assessment of patient behaviours, needs or preferences (Strachan et al., 2014), so this research enlisted a co-design process which had the strength of assessing patient needs throughout the development of the app. Initially in Phase I, the experience of seven patients and four family caregivers was collected, analysed and represented through design artefacts. However, during the usability study in an exploration of patient experiences using the app for heart failure, patient participants reported not being further supported in self-management. Participants rated overall app quality as 'acceptable', slightly higher than 34 comparable heart failure support apps in a recent review conducted by Masterson Creber et al. (2016). Therefore, it is unlikely poor app quality impacted participant experiences using *Care4myHeart*, at least relative to other available apps. IQVIA Institute for Human Data Science (2017) report that consumer ratings of mHealth app quality are often low so improvements in quality is needed across a wide range of consumer apps.

Daily heart failure self-management routines of participants in Phase III were already established which is in contrast to published literature. For example, in a qualitative meta-synthesis of 45 studies Strachan et al. (2014) described the uncertainty patients experience applying heart failure recommendations and knowledge to the context of their daily lives. Health-related routines evolve over time through decision-making and reflection, gaining experience managing their symptoms and subsequent confidence with heart failure self-management (Jaarsma et al., 2017). Phase III findings indicate that once these routines are established, adding technology to practice self-management has no added benefit. Moreover, participants communicated adequate heart failure knowledge meaning they did not learn new content whilst using the app. Similarly, in an evaluation of their heart failure support app, Athilingam et al. (2016) discovered that only 20% of patient participants

reported learning something new. Consequently, self-management apps may be more valuable for patients commencing on a self-management regimen (as suggested in Publication 8, section 6.4) or for younger and newly diagnosed patients (as per clinician responses in Publication 9, section 7.2).

Similar to the findings from the review by Masterson Creber, Hickey, and Maurer (2016), the current research found patients with heart failure are not a homogeneous patient group and evaluating the desires of people with heart failure before introducing an app for self-management is needed. The *Care4myHeart* app was perceived as useful 'for others', but not for study participants. This concept was eloquently captured in the quote: 'I didn't use everything but I can see other people could find it very useful' (participant 1, Phase III). Although Phase I and II participants saw potential for the app to aid self-management, in the reality of daily life, Phase III participants did not use many app features. As with heart failure self-management generally, and as uncovered by Jaarsma et al. (2017), if patients see clear benefits such as reduced symptoms and improved quality of life, they may be more motivated in self-management. More work needs to be done to determine the target subset of consumers who would be most likely to personally benefit from improving their self-management practices and how to access these potential users. Additionally, barriers to technology use in heart failure, and for older adults, have been documented by Masterson Creber, Hickey, and Maurer (2016) and include physical limitations, cost, technology self-efficacy, technology experience, workload of device use, manual data entry and training. Therefore, conducting an assessment of patient acceptance of using technology for the purpose of condition self-management is required prior to app use.

Quality of patient engagement in co-design was more important than quantity. It was initially interpreted that the co-design methodology required active patient and family caregiver engagement throughout the development process, hence retention of all involved in Phase I was a priority. However, it was later realised involvement during key stages in Phase II was adequate to produce the final design with just four patient and family caregiver participants. This challenges the description of co-design by Blomkamp (2018a) who differentiates it from 'human-centred design' because of the *active* role of participants throughout the journey rather than just consultative in a process whereby stakeholders are only minimally involved. Examples from this research demonstrate that success should not be measured by how many participate from start to end, rather, strategies to maximise their perspectives are most beneficial. First in Phase I, the diverse, unpredictable world in which patient self-management occurs (Strachan et al., 2014) was captured using the chosen methodologies. Design artefacts (personas, journey map and stakeholder map)

were successfully used in this context, confirming that documenting patient narratives legitimise their preferences (Ekman et al., 2011) even when they are not present in design workshops. Moreover, the empathic approach to data collection captured the day-to-day accounts of how illness was experienced, the symptoms, their suffering and the impact on life which is often omitted in the medical narrative (Ekman et al., 2011). Then in Phase II, specific strategies accounted for lower patient participation. For example, the patient perspective was front and centre in workshop activities where participants worked with design artefacts and the design brief. Further, power-balancing techniques such as 'supervoting' meant that patient perspectives were prioritised. The research reported in this thesis presents a strong case that co-design should use patient and families only as needed and leverage design techniques to maximise their contribution.

Formalised recruitment may have limited the variety of perspectives to be incorporated. Attempts to represent the diversity in the nonhomogeneous patient population was limited by self-selection as only those willing to participate in research could be included. Notably, Phase IV uncovered that for patients engaged until the project's completion, participation was an opportunity to give back to the health service and felt 'honoured' and 'glad' to be involved. But ethically, how can partnerships in shared decision making be developed, as suggested by Ekman et al. (2011), without adequately respecting patient and family participation? Hence, researchers need to work hard to respect and encourage participant involvement in co-designed research. This is especially challenging when involving participants with a life-limiting chronic illness in research over many months. Willis et al. (2011) explains their experiences involving patients with chronic respiratory disease in a 12-month study of a complex self-management intervention. Research participation imposes an additional burden to those who may already be overwhelmed by medical and care issues so maintaining engagement for a prolonged period in these circumstances is difficult (Willis et al., 2011). Authors (Willis et al., 2011) describe research participation was for altruistic reasons. While not specific to the context of chronic conditions but to the healthcare sector more generally, Hendricks et al. (2018) proposed a new stakeholder participation assessment framework for Design Thinking projects, during the conduct of this study. Information gained from evaluating participation in a Design Thinking project could be used to increase participation and result in greater update of the resultant innovation (Hendricks et al., 2018).

Participants did not experience involvement from family caregivers when conducting self-management using the app, yet they were the most involved stakeholder in conducting self-management in the Phase I cohort. While very few heart failure interventions have assessed

caregiver roles in the design (Burke et al., 2014), one contribution from this research which did incorporate caregivers in the design phase, was a duplicate app for family caregivers. A read-only interface would be accessible to caregivers in a different geographical location (via consent) allowing them to 'check in' on their loved one and be alerted to signs of worsening heart failure. This was not tested in the usability study. Nevertheless, participants reported no involvement from family caregivers in using the patient-facing app in the usability study. Consequently, this research demonstrates the need to meaningfully integrate caregiver perspectives in a consumer app to make it beneficial to both the patient and caregiver. If heart failure self-management interventions are to intentionally address caregiver involvement (Strachan et al., 2014) rather than expressed through a third party, then innovative designs like a read-only app, need to be explored. Secondly, examining the existing literature would be particularly insightful for intervention design. For example, caregivers frequently detected subtle changes to the patient condition through constant patient observation (Strachan et al., 2014) and interestingly, caregivers often view themselves as the primary care providers for their loved one with heart failure with the health system enabling that care with suggestions and recommendations (Burke et al., 2014). These are a few examples of how caregivers view their role and understand their position within the home and healthcare ecosystem. Support for optimal care in the home setting is a priority (Burke et al., 2014) as heart failure is a complex condition associated with a clinical decline as the condition progresses (Strachan et al., 2014). To this end, caregivers must be key stakeholders in any intervention aimed at supporting people with heart failure.

8.2 Clinician stakeholder group

Key finding

Clinicians were easily recruited, highly engaged and continued participation throughout the co-design process.

Clinicians were easily-recruited, motivated research participants. From the beginning, clinicians aspired to develop an app as a self-management tool in addition to existing heart failure care. This conforms to the recommendation for consumer apps to be paired with ongoing healthcare professional input by Anderson and Emmerton (2016). Their review explored the contribution of mHealth apps on chronic condition self-management and implications on Australian health policy, procedures and guidelines (Anderson & Emmerton, 2016). Similar to the scoping literature review

findings (Publication 1, section 2.3), clinicians reported contextual need for greater support of patients undertaking self-management.

In contrast to the literature, clinicians actively participated in each development stage. In other studies involving mHealth development processes (Publication 1, section 2.3), a 'requirement analysis' was conducted in the pre-design phase with local staff who provide care in a specific healthcare context. But during the initial design of these apps, healthcare professionals were not involved, rather, the initial designs were formed by research teams, software developers or experts. In this research clinician recruitment, retention and participation was high throughout the whole development process. Rationale for ongoing research engagement was uncovered in Phase IV: clinicians felt participation was a research engagement opportunity and an interesting learning process. The ongoing involvement of clinicians was beneficial in increasing the likelihood of supporting patient self-management through a tailored design consistent with existing policies, guidelines and current healthcare delivery models. The co-design process itself provided clinicians a means to empower them to improve the experience of giving care as proposed by the Experience Based Co-design process (Dawda & Knight, 2018).

Clinicians highly regarded the final app design. Phase IV uncovered positive experiences of participation reported by clinicians who thought the structured development approach with regular feedback, was efficient. Most were pleasantly surprised at the quality of the design outcome. Clinician 5 described how the app may be used: 'I see it will be a wonderful tool to support heart failure patients and their family and clinicians'. Clinicians particularly appreciated the perceivably simple, easy-to-use interface and modular design. However, these findings are to be interpreted in the context in which the data was uncovered, as these findings indicate that those involved in co-design are loyal to the design outcomes. Thus, design outcomes should be tested on a new subset of patient-users to identify as many usability and usage issues as possible as recommended by Tatara, Årsand, Bratteteig, and Hartvigsen (2013). The authors report their study design which involved patients in the initial design of a mHealth app for diabetes self-management and then in a 5-month usability study to continue to iteratively refine the design based on patient feedback (Tatara et al., 2013). Although more resource intensive, the format of including different patients at different development phases confirms the suitability of the research design reported in this thesis.

This research demonstrated the successful application of the 'Rose, Thorn, Bud' technique to gathering healthcare provider needs and confirm it was an appropriate method to gather perspectives and opinions from this stakeholder group. The technique allowed quick responses,

initial codifying of data and an opportunity to express thoughts and develop ideas prior to group activities. Importantly, it limited clinician time away from providing care so participation was viable within their existing workloads.

Nurse practitioners voiced concerns about the implementation of the *Care4myHeart* app. No heart failure self-management app was recommended to patients in the local heart failure service during the time of the study which was an impetus for this research to be conducted. Once it was developed, nurse practitioners who lead the heart failure service in the hospital, had several unanswered questions about the next steps for planning for implementation listing legal, funding and health fund issues. Consistent with the literature, mHealth apps are not yet established for widespread and sustained use nor embedded in Australian health policy (Anderson & Emmerton, 2016) so these concerns were warranted. Accuracy, efficacy and security concerns (IMS Institute for Healthcare Informatics, 2015), and the inconsistent impact on disease control (Hanlon et al., 2017) limit the addition of consumer apps to healthcare treatment protocols (IMS Institute for Healthcare Informatics, 2015). Most are developed outside health care systems (IMS Institute for Healthcare Informatics, 2015) and some may even threaten patient safety and privacy (Whitehead & Seaton, 2016) further limiting clinician endorsement. Regardless, nurses are well suited to upskill to recommend and integrate apps into clinical practice, and importantly, ensure the apps used by patients contain relevant evidence-based and up-to-date information (Ferguson & Jackson, 2017).

The strength and focus of this research was the rigorous development and real life usability study, not an implementation study. Consequently, when clinicians were asked about clinical requirements in Phase I, their responses were relevant to *developing* the app with no responses relating to implementation. Nevertheless, when implementation concerns were uncovered in Phase IV, chosen methodologies were compared to other innovation frameworks to see if they had a greater emphasis on implementation. This analysis uncovered different approaches to assist with implementation once the product is ready for widespread deployment, for example, the 'monitor and maintain' component of the Experience Based Co-design approach (Dawda & Knight, 2018) and the 'tool optimisation, release and scaling' phase of the Process Model for User-Centred Digital Development (Chokshi & Mann, 2018).

8.3 Lead clinician researcher as stakeholder

Key finding

Leading a highly structured innovation process allowed efficient development of the application.

Executing the clinician-led research project required strong leadership and commitment. Highly-structured design activities ensured the progression through the ideate and prototype development stages (reported in Phase II). When questioned, stakeholders confirmed they appreciated the highly-structured design approach (reported in Phase IV). Regular feedback on the prototype, ongoing communication from the lead clinician researcher and quick, flexible co-design activities were particularly positive. This was only achieved through co-design leadership and project management by the lead clinician researcher.

The benefit of leadership in co-design projects was highlighted in the recent review by Clarke and colleagues on co-produced or co-designed projects in acute care settings (Clarke et al., 2017). They report the clear benefits to the formal and funded facilitator role discovering that it was more likely the co-design project: maintained momentum and was delivered as planned; retained co-design participants; and generated particular examples of required improvements to staff and patient experiences (Clarke et al., 2017). Also consistent with the findings from the scoping review (Publication 1, section 2.3), the authors (Clarke et al., 2017) uncovered that facilitators of co-design projects were researchers or designers. This suggests that although clinicians are commonly engaged in healthcare co-design projects, they do not often lead them and demonstrates the contribution of this research to the body of knowledge.

Discovering the art and science of design was powerful for this evolving area of research. Clinicians can use the Design Thinking approach and use practical and creative design methods to improve healthcare. Rightly, Design Thinking is emerging in healthcare because it offers healthcare teams a set of tools to help collect, analyse and incorporate experiences in new interventions (Roberts et al., 2016) and this is becoming evidenced in the literature. In the aforementioned review (Clarke et al., 2017), healthcare teams have benefited from new ways of thinking and working together through activities unfamiliar to most healthcare professionals like metaphor games, design experiments, prototyping and visual storyboards. In this research the use of empathy, journey and stakeholder mapping and patient personas showed how to help reveal knowledge that is emotional, non-linear, holistic and intuitive as suggested by Blomkamp (2018a). This was unlikely to be revealed through

traditional data collection methods. The use of design artefacts in workshop activities facilitated conceptual design and iterative development processes. For example, frustrations and challenges in the patient experience were represented in patient-modelled personas from participant interviews. Colour, layout and carefully selected quotes represented a holistic patient picture, adding subjective data to objective measures. In a practical sense, personas facilitated discussion from the same understanding of context and needs, as advocated by Nielsen (2011), a well-published author on personas in user-centred design. Personas then acted as input for the subsequent app development phases that facilitated the progression of the app development. This research illustrates that design artefacts can be successfully used in intervention design for heart failure. Further, research outcomes strongly suggest the use of design artefacts for any intervention or service re-design and should not be limited to digital health development.

Regardless of how meaningful these accessible, creative representations were in representing diverse and complex experience data within a healthcare context, there is limited information about the costs and resources associated with carrying out co-design activities in existing studies (Clarke et al., 2017). This may be in part due to the early stage of adoption in the healthcare sector (Clarke et al., 2017). Moreover, a common criticism of co-design processes is that it is too time consuming (Donetto et al., 2015). Although the co-design journey was nine months (similar to the expected timeframe for the accelerated Experience Based Co-design version (Donetto et al., 2015)) the time commitment of the lead clinician researcher is not to be understated. 'Design' was a new research domain as a clinician. Research data uncovered through rigorous qualitative inquiry was embedded into design artefacts. However, studying, selecting and executing design activities, then compiling and representing data for each design phase, was a full-time commitment for a clinician researcher with no previous design experience. Outside a doctoral program it is unlikely clinicians have the means to conduct a similar co-design project without human, financial and management support. In other busy, acute healthcare settings, lack of support, resources or managerial authority are documented barriers to the success of co-design projects (Clarke et al., 2017). If we are to address healthcare problems with these creative, visual and collaborative methodologies then sufficient resourcing is imperative for their successful facilitation. This would require institutional leaders to embrace innovation, empower staff and release them from their regular hospital duties to conduct and complete co-design projects.

Undertaking the research required navigating the competing priorities of being a clinician, researcher and developer. Recognising the multiple roles a co-design facilitator could play in a

clinician-led development project, should be recognised. Primarily, as a *clinician* the motivation was trying to provide the best intervention for the local patient population. Conversations with clinical colleagues and patients revealed the appetite for an app as the intervention to support patient self-management, so the project evolved. Secondly, as a student *researcher* the project was formalised as a research study, requiring a suitable doctoral study design and associated ethical approval. Concurrently, funding partners expected the design outcome to be a mHealth app as outlined in the approved grant application. Tension may have resulted if the co-design team wanted to design an intervention that was not a mHealth app. Finally, viewing the research findings from a third perspective as an app *developer*, would call for a recommendation to refine the user interface through design improvement cycles conducted with a broader, less homogeneous user sample. These competing agendas were adequately negotiated in this doctoral research and a stable, functional app was produced and tested as per the study procedures. However, reflecting on the usability study findings and to be consistent with the Design Thinking process, *Care4myHeart* needs further ideation, prototyping and testing. Accordingly, this research confirms that there is no one, easy answer to complex health problems, but a Design Thinking framework of innovation, through a process of learning (and failing), can help drive necessary changes in care delivery that is better aligned with consumer needs (Roberts et al., 2016).

8.4 Stakeholder interactions

Key finding

Co-design methods helped negotiate tensions between stakeholders in the design.

Overall, stakeholder interactions were effectively managed confirming that local app design can be achieved through partnering with patients, family caregivers and clinicians. This thesis listed, described and evaluated various stakeholder involvement processes used in the design and development of the app. Publication 7 (section 6.2) presented a detailed discussion on the strategic incorporation of different stakeholders in each development stage. Stakeholders were individually interviewed in Phase I, then brought together in collaborative workshop activities and independently consulted in design iterations (Phase II). This leveraged the strengths and perspectives from different positions within the health service into the design, also taking into consideration the technical requirements and limitations which evolved through the iterative development.

Effective collaboration among stakeholders with differing interests is necessary for mHealth design (Matthew-Maich et al., 2016). Careful negotiation of perspectives was required in planning for a patient-centred, consumer-facing app which aimed to support people with the condition to self-manage their condition outside the health service, but still incorporate healthcare provider perspectives. Addressing various stakeholder needs was pertinent in Phase I and II while the effectiveness of this negotiation was evidenced in Phase III and IV. This research confirmed that adopting a Design Thinking methodology and co-design principles provided a format of radical collaboration across opposing mindsets as proposed by Roberts et al. (2016). The methods used fostered democracy and equality rather than hierarchy and patriarchy. For example, Donetto et al. (2015) who have reflected on various Experience Based Co-design projects in healthcare, found that bringing stakeholders to work together can result in a renegotiation of roles within the health service. Further, Ranerup and Hallberg (2015) discovered during developing an app for hypertension self-management, that the universal scientific knowledge can be suitably balanced against the lay knowledge if provider, patient and researchers work together. As suggested by Skeels and Pratt (2008), the 'guide without dictating' design philosophy was adopted for this research as a deliberate and strategic practice. Selecting the right tools and techniques, with the right stakeholders at the right time leveraged the expertise available in the clinical environment in this research. A skilled co-design facilitator chooses the right tools and provides the right environment for engagement and inspiration (Blomkamp, 2018a) so understanding which design techniques were suitable for which stakeholders to achieve design milestones was a learning process, but was achieved in this research.

Co-design tools and techniques provided a format to account for power differences between healthcare professionals and healthcare consumers. All relevant perspectives to be incorporated in the design exist in healthcare settings with inherent power imbalances (Burford et al., 2015). Consequently, in their paper describing a method for participatory design in mobile health Burford et al. (2015) maintain that structured methods are needed to ensure engagement processes are democratic. Power imbalances were managed in the design of *Care4myHeart*. For example, a 'supervote' was given to the only patient who attended the design workshops. Adapted from a design sprint activity (Knapp et al., 2016), a supervote placed next to a design concept gave it more weight, representing a higher design priority than those without a supervote. The technique was used to favour the patients' perspective over the clinicians', as the target end-user of the app is more appropriately positioned to make decisions about the user-interface. Power imbalance was noted even prior to when the research was commenced. Ethical requirements listed 'clinicians as investigators' and 'patients as participants' which was a research requirement that contradicts the

patient-empowerment movement and principles of co-design. To truly reflect the emerging priority to incorporate consumers in healthcare improvement efforts as active, empowered research partners, then remuneration and other incentives need to be considered. Unless every stakeholder is adequately recognised for their time and efforts, they are not adequately respected nor considered equal partners in co-design. Although patients were found to be motivated by 'contributing back to the health service' as uncovered in Phase IV, this is not enough recognition for time spent in participation.

Perhaps the most significant influencing factor signifying the need to negotiate tensions was the ongoing participation of clinicians. The literature review uncovered that healthcare professionals were less involved than patients in developing mHealth interventions for chronic condition self-management, however we experienced the opposite whereby clinicians wanted to be heavily involved. This needed to be accounted for in Phase II so design artefacts were used to counteract disproportionately low patient participation. Design artefacts communicated Phase I findings (where 11 patient and caregiver experiences were captured) to participants involved in Phase II (where only 4 patient and caregivers were involved). Lupton (2018), who researches the interaction between human and non-human things, suggests that design artefacts challenge perceptions and raise questions about conventions and assumptions. This research confirms the application of design artefacts in digital health co-design projects, particularly when the patient and family perspective is underrepresented.

A method for stakeholders to decide on priority design features as the development unfolded was not established, so the design included all possible features. At best, this resulted in a user interface representative of the design teams' collective decisions in order to gather suggested changes for improvement from the perspective of the uninitiated user in the usability study. At worst, this resulted in a busy user interface and many app sub-sections which could overwhelm a potential user. Although the modular design which evolved through design iterations hoped to overcome this perceived problem, Phase III findings indicated patients are only likely to use one or two features regularly. Future iterations could address this design concern, further emphasising the need for agile, iterative processes in refining the design beyond the completion of this research.

Finally, stakeholder selection was more influential to the design outcomes than initially anticipated. As explained in Publication 7 (section 6.2) those involved in the design impacted the design outcomes. Further, Publication 9 (section 7.2) discussed the significance of forming meaningful, appropriately-sized co-design teams. This conforms to Ranerup and Hallberg (2015) who suggest

that the intentions of the members of development teams influence the technology and the development process itself. Thus, the convenience sample of self-selecting patients and family caregivers and purposive sample of multidisciplinary clinicians subtly influenced the final design. Uncertainty about the 'ideal' co-design team was evidenced in Phase IV, as some co-design participants wanted more perspectives to be involved although they appreciated the diversity of perspectives already incorporated.

8.5 Contributions

This section provides a reflection on the contributions this research has made to the existing knowledge on mHealth research, co-design practices and stakeholder engagement. This thesis has brought an original contribution of knowledge which have relevance to clinicians, patient and family members, researchers, app developers and for policy. The contribution to knowledge is presented at three levels: substantive; methodological; and theoretical.

At a substantive level, this research has provided a thorough investigation on whether patients with heart failure can be supported in self-management through a mHealth app co-designed by patients, family caregivers and clinicians. The scoping literature review (Publication 1, section 2.3) revealed limited descriptive detail on design processes of mHealth interventions for chronic conditions, at least in the literature available to clinicians. The publications contained in this thesis, most of which are open access, provide a detailed description of how consumer mHealth apps can be designed and developed by healthcare teams inclusive of patients and family caregivers. The content in the developed personas, journey map and stakeholder map is research data contributing to further understanding the many ways heart failure self-management is conducted in the home setting. Once the app was built, a justification of the app components was provided, based on the findings elicited from the co-design process. The strengths and limitations of incorporating stakeholder experience data and the evidence-based literature, on the final design was presented. Phase IV findings add to the body of knowledge on stakeholder perspectives of the co-design process, clearly reported as successes and failures. Motivation for participation and opinions on the design outcomes was presented.

At a methodological level, the research design has demonstrated the value of structure, leadership and adoption of design methodologies outside of the traditional nursing paradigm. The Design Thinking process was successfully used to uncover the needs of various stakeholders, design and develop a solution and test it on patients. The process enlisted resulted in the production of a functioning mHealth app within nine months. This thesis has contributed to the methodological

approaches to: collect and represent experience data for the purpose of designing healthcare interventions; explain a pathway for clinician-led mHealth co-design within a health service; and use rapid design methods to gather, analyse and represent experiences. This study demonstrates design artefacts can be used successfully for intervention design in heart failure. Empathy, journey and stakeholder mapping and patient personas are examples how design artefacts can give voice to the frustrations and challenges patient experience, and represent diversity in the patient experience. Personas are a valuable method from consumer marketing which should be more widely adopted for use in patient experience research in the health sector. In workshop activities design artefacts were helpful for the conceptual design activities and then the use of wireframes provided a tangible prototype in which meaningful feedback could be provided. Methods of engaging with healthcare teams (including patients and family caregivers) through adopting co-design principles and Design Thinking practices has been explored and critiqued. Although clinicians are commonly engaged in healthcare co-design projects, they do not often lead them, so this research has contributed to the emerging body of knowledge how to facilitate co-design workshops and associated activities from within a health service as a clinician. The usability study design incorporating a mixed-methods evaluation provided a rich, thorough analysis of the phenomenon surrounding the patient experiencing using the app for self-management. Therefore, the 14-day period and relatively small sample size was adequate to address the objective.

At a theoretical level, the research has highlighted important findings for each of the stakeholder groups involved in the study. Importantly, this thesis plays a role in initiating a discussion around clinician-led co-design and embedded innovation. Healthcare clinicians are becoming increasing aware of the high costs of healthcare, the ageing population, the aim to deliver the best possible care and to support patients to be at the centre of their care. Clinicians can lead the change if empowered to do so, through managerial support and leveraging their skills. For patients, this research contributes to the theory about patients as members of co-design teams in terms of their motivation to participate and ways to maximise the quality of their engagement. This research also contributes to the understanding of barriers to technology acceptance in the context of heart failure self-management for people with established self-management routines. Notably, these findings expand the phenomenon surrounding the behavioural implications between humans and health technologies. Rich, meaningful research findings and suggested changes in the user-interface design were uncovered through a relatively small sample of six patients, contributing to the theory on usability studies for consumer apps. Theory on the interaction between stakeholders in a healthcare team involving co-design has been further explored in this research including an investigation of

tensions and power imbalances involving various stakeholders. Further, selection of those involved in the co-design project has influenced the final design further contributing to the theory on multi-stakeholder mHealth co-design.

8.6 Implications

Researchers and developers would collectively benefit from the research outputs and lessons learned from this research. These aspects are important to understand if healthcare providers want to overcome the design challenges of a new interventions that can positively improve healthcare outcomes.

Executing a co-design project is about stakeholder management, so ways to lead others and negotiate tensions between those involved in the design would be valuable. Understanding stakeholder motivations for participation aids participant recruitment so these need to be leveraged in other co-design projects. For example, co-design was a research engagement opportunity so participation in a co-design healthcare improvement project could contribute to the 'Continuing Professional Development' points required by the Australian Health Practitioner Regulation Agency. Also, healthcare teams need to carefully choose how to ethically and respectfully engage service users in redesign efforts. New ways to increase consumer engagement in co-design projects is needed. Once the team is formed, participants will appreciate co-design activities that are quick, flexible and involve encouraging, ongoing communication. Involving many stakeholders in the design can be beneficial from many important perspectives but facilitators need to select a meaningful, manageable, appropriately-sized co-design team.

The research domains of user-centred design and human-computer interaction offer dynamic, practical and innovative methods which would be beneficial for development teams involving, or led by, clinicians. Without adopting methodological theory from domains outside of health including the complex socio-technical environments in which patients live, resultant designs will likely fail to realise their potential to improve health.

Research findings reported in this thesis have implications for usability studies involving consumer mHealth apps. Consequently, the following recommendations result from conducting this research: test and re-test the software prior to patient use; avoid version updates to limit confusion; and consider recruiting 'early adopters' of health apps because learning new technology on top of managing daily health routines may be unachievable.

Finally, for clinician-led research, implementation planning should be more prominent. Co-designing an implementation strategy alongside the co-design of the digital health product would address important policy, organisational or financial restrictions which inevitably impact the app ever reaching consumers.

8.7 Limitations

All knowledge in this research is context-specific, experientially based and constructed through social interaction. The research was highly active, involving qualitative inquiry, collaboration and leadership so the role of student researcher cannot be dismissed. Data was primarily interpreted by a clinician embedded in the health service who led the design research with limited knowledge that grew as the research progressed. Accordingly, the strategic selection of the chosen methods demonstrates the trustworthiness of the findings. Data collection and data analysis processes have been meticulously explained in the methods chapter and within the publications arising from this research, specifically how the findings accurately reflect the data.

As qualitative researchers, research findings may be relatable to other settings but not necessarily generalisable. Data were collected from a local sample of patients, family caregivers and clinicians, so other researchers need to judge how the findings may relate to them and their circumstances. Of note, participants were recruited from a cardiac-specialist hospital with a well-established multidisciplinary heart failure care team which may have impacted the patient experience of receiving healthcare in the first instance. Further, clinicians participating in this study were familiar with facilitating research studies, hence this could have biased the findings in regard to their engagement in, and perspectives on, the research. Regardless of these context-specific factors, the findings may hold significance beyond the setting in which the study was carried out (Parahoo, 2014). Adopting the user version of the Mobile Applicating Rating Scale would have aided the comparison of usability study results to other studies, but unfortunately, only the original version of the Scale was available.

As previously highlighted, and consistent with other co-design projects, the findings are limited by participant self-selection and ongoing involvement in the research. For example, no family caregivers attended design workshops, a small number of participants were involved in refining the prototype and only males chose to participate in the usability study. Whilst clinicians were involved from the project initiation to completion, just one patient participant participated in all design activities as they were the only one who chose to attend the design workshop. Moreover, less adherent patients who could most benefit from self-management support, may be less likely to be research

participants and may report different experiences to those in this research both during the co-design and in the usability study.

8.8 Future directions

Future research should explore in what formats and contexts mHealth apps can positively influence the heart failure self-management activities patients carry out in their daily lives. Specifically, research should further investigate Phase III research findings regarding the role of mHealth apps to improve self-awareness and continuous learning, ways for patients to better manage their health information across the healthcare system and how mHealth apps can be designed to limit technical challenges before they are deployed to patients. Third party access to medical information, especially in an emergency, would also be of benefit and should be investigated. Future studies should investigate the barriers to adoption and sustainability of consumer mHealth apps and whether introducing such apps would be more beneficial: a) at the commencement of a self-management regimen; b) for newly diagnosed patients; or c) younger patients.

The caregiver experience in consumer health technology development is an important area for future research. Possible research questions include: What is the experience of family members in patient-facing technologies for chronic conditions?; How can development teams effectively incorporate caregiver perspectives on the current and desired caregiver role?; and, Do duplicate, read-only caregiver apps support chronic condition self-management?

There is appetite to engage more service users into healthcare improvement projects so future research is needed to empower clinical teams to operationalise co-design in practice. Frameworks for the development of mHealth need to be further established, and made available, to ensure quality and safety of health apps. This thesis has reported a reflection of the Design Science Research Cycles and Design Thinking process. While these methodologies have been effective in guiding the app development, other methods would be needed to further evaluate the app incorporating implementation and sustainability phases. Applying evolving frameworks for assessing stakeholder involvement in co-design or Design Thinking research, could be used to better leverage consumer involvement of research focused on end-user experiences.

Many lessons were learned from this research which should be tested and advanced in other clinician-led innovation projects. This study highlighted there is much complexity when co-designing a novel intervention within a health service. Particular challenges include stakeholder selection and management. The application of co-design and Design Thinking to other upcoming healthcare

improvement projects on hospital campuses would be beneficial, regardless if the projects were technologically focused or not. Hospital managers may view the contemporary method as a meaningful way to engage stakeholders to address shared healthcare challenges and improve patient experiences. But, as reflected in the literature, operational and financial support is required, therefore ways for healthcare co-design teams to maximise outputs should be trialled along with cost-benefit evaluations.

Implementation science involving mHealth apps for chronic conditions is an important area of research and development. Implementation concerns were raised by the nurse practitioners who lead the local heart failure service. The use of mHealth in the self-management of heart failure is relatively new and not embedded into practice, at least in the context in which this app was developed. There are many questions which clinicians, organisational leaders and policy makers need to address for its integration into the health service. It is likely we are a long way from a change in policy which sees clinicians critiquing, selecting and prescribing health apps. Should clinicians be involved in the selection, deployment and monitoring of consumer apps, successful implementation would require a financially sustainable reimbursement model for healthcare providers. This model would incorporate funding to monitor people outside the walls of the health service blended with face-to-face care at times of need. This is unlikely to occur without a definitive study to describe the clinical impact of the app on heart failure self-management.

In regard to the app, the research team have already uncovered important considerations for the future design not possible with the current version. Suggested changes identified by participants in Phase III were relatively minor to incorporate in the next version of the app. The next version would include greater flexibility over patient-entered data, more features applicable to the target condition and a more appealing user interface.

8.9 Concluding remarks

Mobile health is expanding with the ubiquity of technology in the contemporary era. Consumers now have the option to receive healthcare through their mobile devices, but currently consumer apps vary in quality and are not yet embedded in healthcare policy. The body of knowledge on the design, development and evaluation of consumer mHealth apps for chronic conditions is developing. Rigorous research facilitates the quality and safety of these apps which aim to improve patient outcomes.

This thesis contributes to understanding how to operationalise mHealth co-design within a health service. Meaningful partnerships with patients, family caregivers and clinicians resulted in the successful design and development of the *Care4myHeart* app and the design outcome was highly regarded by the co-design team.

More work needs to be done to understand the socio-technical interplay between people with heart failure (or other chronic conditions) and consumer health technologies. This research has demonstrated success in the development of a comprehensive, evidence-based app, but if it does not further contribute to heart failure self-management, acceptance and adoption are barriers limiting their potential.

Operationalising co-design was achieved through adoption of a highly structured Design Thinking and co-design methodology, successful negotiation of tensions between stakeholders and use of design artefacts. These approaches should not be limited to digital health technology development and should be applied to other healthcare domains. Research reported in this thesis illustrates that clinicians can lead co-design processes, successfully partner with local staff and consumers, and make embedded innovation and quality improvement possible.

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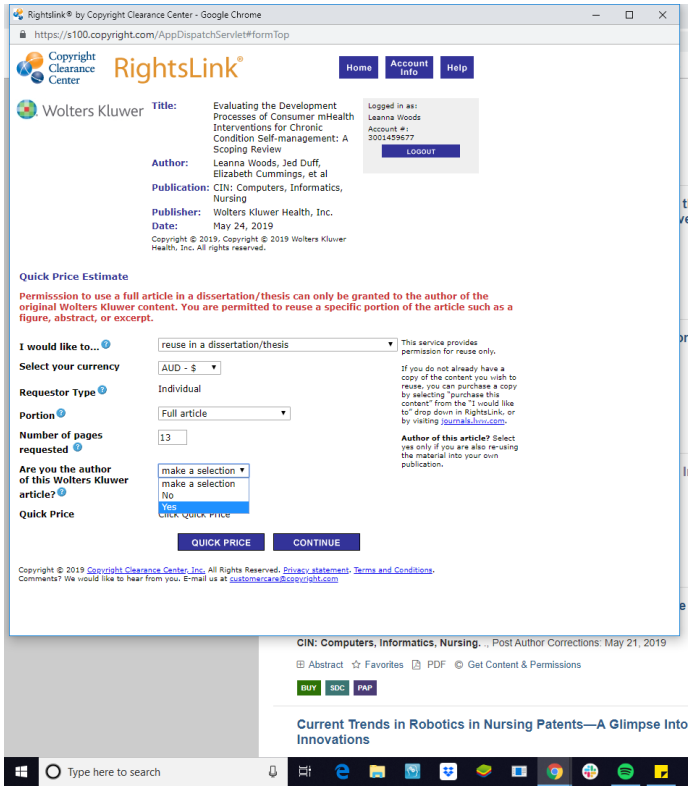
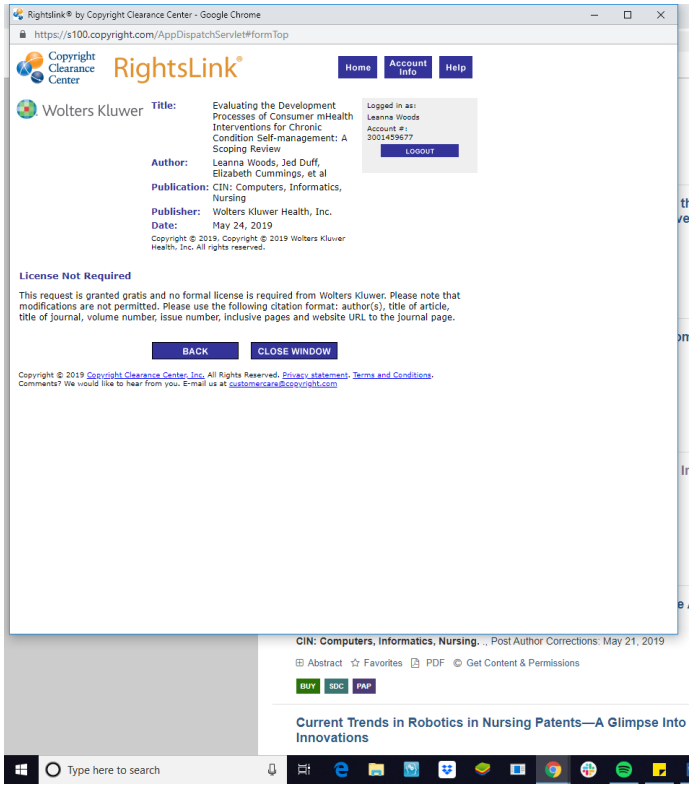
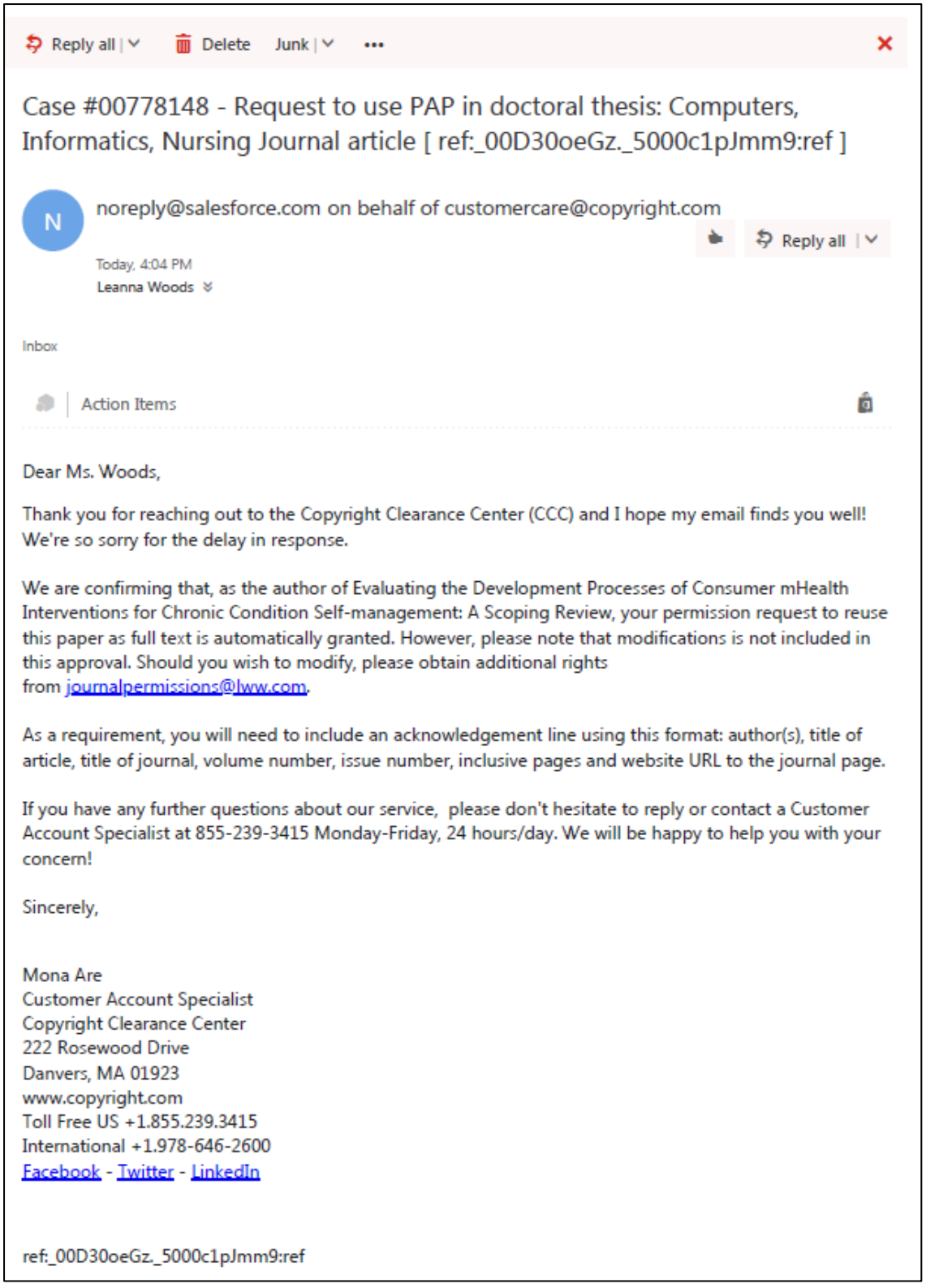
Appendix

Appendix A Approvals to use publications in this thesis

Publication approval from Computers, Informatics, Nursing – Publication 1







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Today, 4:04 PM
Leanna Woods

Inbox

Action Items

Dear Ms. Woods,

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Publication approval from IOS Press - Publication 2, 4, 6 (and Publication 9 which is in press)

RE: Request to include publications in PhD dissertation

CK Carry Koolbergen <C.Koolbergen@iospress.nl>
Fri 8/03, 11:52 PM
Leanna Woods; Liz Cummings

Inbox

DOI 10.3233/978-1-61499-794-8-97
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Verzonden: dinsdag 5 maart 2019 3:41
Aan: Carry Koolbergen <C.Koolbergen@iospress.nl>
CC: Liz Cummings <elizabeth.cummings@utas.edu.au>
Onderwerp: Request to include publications in PhD dissertation

To whom it may concern,

RE: Request to include publications in PhD dissertation

I am the lead author of the following manuscripts which have been published with *Studies in Health Technology and Informatics*;

1. Woods, L, Cummings, E, Duff, J & Walker, K 2017, 'Design Thinking for mHealth Application Co-Design to Support Heart Failure Self-Management', *Studies in Health Technology and Informatics*, vol. 241, pp. 97-102.
2. Woods, L, Cummings, E, Duff, J & Walker, K 2018, 'Conceptual design and iterative development of a mHealth app by clinicians, patients and their families', *Studies in Health Technology and Informatics*, vol. 252, pp. 170-175.
3. Woods, L, Cummings, E, Duff, J & Walker, K 2018, 'Partnering in digital health design: Engaging the multidisciplinary team in a needs analysis', *Studies in Health Technology and Informatics*, vol. 252, pp. 176-181.

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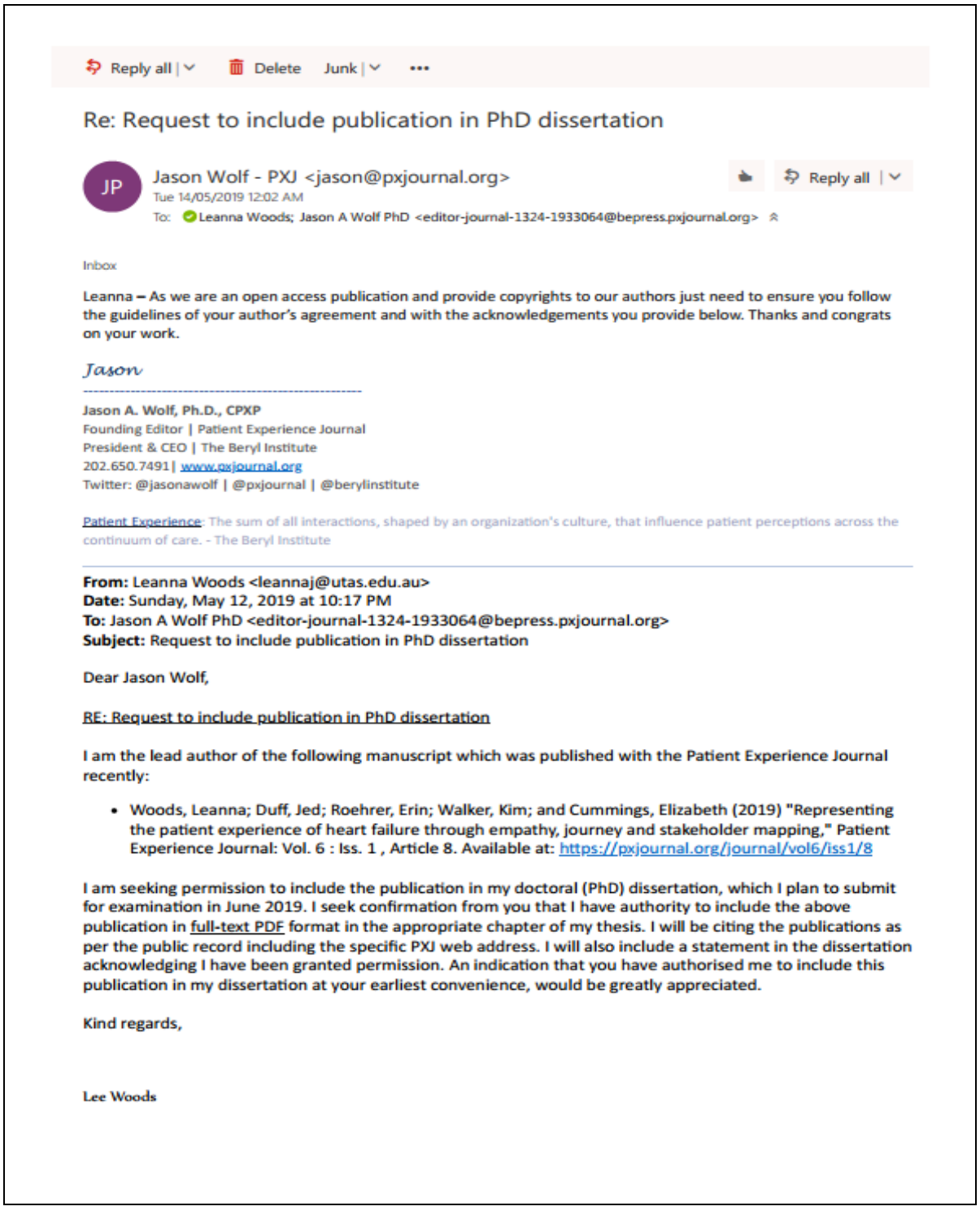
Kind regards,

Leanna Woods

Clinical Nurse Specialist, Level 6, St Vincent's Private Hospital, Sydney
and PhD Candidate, University of Tasmania, Darlinghurst
P: 02 8572 7930 E: leannaj@utas.edu.au

Publication approval from Patient Experience Journal – Publication 3



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Re: Request to include publication in PhD dissertation

JP Jason Wolf - PXJ <jason@pxjournal.org>
Tue 14/05/2019 12:02 AM
To: Leanna Woods; Jason A Wolf PhD <editor-journal-1324-1933064@bepress.pxjournal.org>

Reply all

Inbox

Leanna – As we are an open access publication and provide copyrights to our authors just need to ensure you follow the guidelines of your author's agreement and with the acknowledgements you provide below. Thanks and congrats on your work.

Jason

Jason A. Wolf, Ph.D., CPXP
Founding Editor | Patient Experience Journal
President & CEO | The Beryl Institute
202.650.7491 | www.pxjournal.org
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Patient Experience: The sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care. - The Beryl Institute

---

From: Leanna Woods <leannaj@utas.edu.au>
Date: Sunday, May 12, 2019 at 10:17 PM
To: Jason A Wolf PhD <editor-journal-1324-1933064@bepress.pxjournal.org>
Subject: Request to include publication in PhD dissertation

Dear Jason Wolf,

RE: Request to include publication in PhD dissertation

I am the lead author of the following manuscript which was published with the Patient Experience Journal recently:

- Woods, Leanna; Duff, Jed; Roehrer, Erin; Walker, Kim; and Cummings, Elizabeth (2019) "Representing the patient experience of heart failure through empathy, journey and stakeholder mapping," Patient Experience Journal: Vol. 6 : Iss. 1 , Article 8. Available at: https://pxjournal.org/journal/vol6/iss1/8

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Kind regards,

Lee Woods

Publication approval from ACM – Publication 5

BR Barbara Ryan <barbara.ryan@hq.acm.org>
Wed 6/03, 12:35 AM
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From: Leanna Woods [mailto:leannaj@utas.edu.au]
Sent: Monday, March 04, 2019 10:15 PM
To: Barbara Ryan
Cc: Liz Cummings
Subject: Request to include publication in PhD dissertation

Good afternoon Barbara Ryan,

R: Request to include publication in PhD dissertation

I am the lead author of the following manuscript which has been published with *ACM series Proceedings of the 29th Australian Conference on Computer-Human Interaction (OzCHI 2017, Nov 28 - Dec 1, Brisbane, Australia)*;

Woods L, Duff J, Cummings E, Walker K. The development and use of personas in a user-centred mHealth design project. In proceedings of *the 29th Australian Conference on Human Computer Interaction* (OZCHI '17), Alessandro Soro, Dhaval Vyas, Bernd Ploderer, Ann Morrison, Jenny Waycott, and Margot Brereton (Eds.). ACM, New York, NY, USA, 560-565. DOI: https://doi.org/10.1145/3152771.3156186

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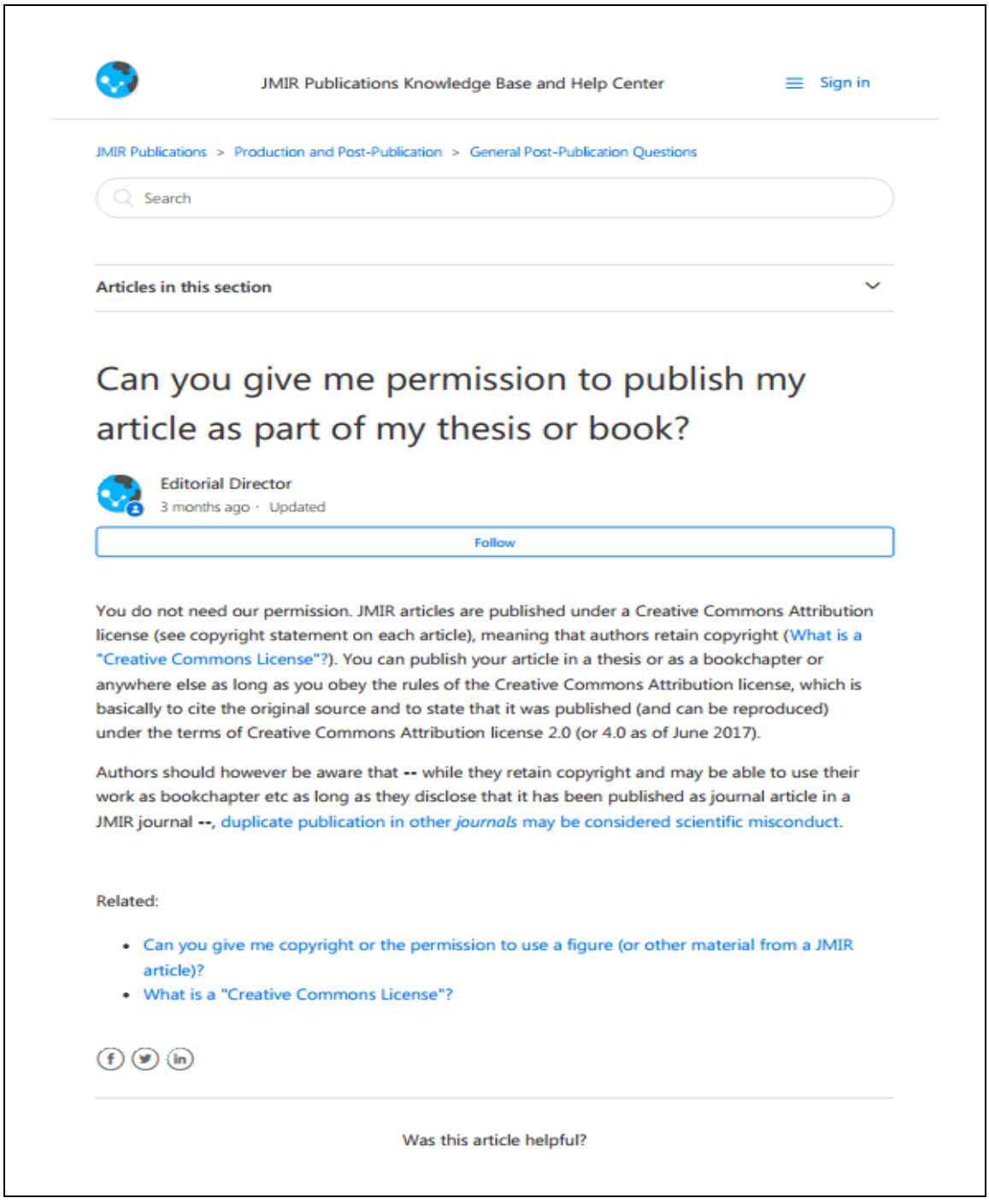
Kind regards,

Leanna Woods

Clinical Nurse Specialist, Level 6, St Vincent's Private Hospital, Sydney

Publication approval from JMIR Human Factors – Publication 8



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Mark as unread

To: Leanna Woods;

You replied on 6/04/2017 4:24 PM.

Bing Maps

Get more apps

Hi Lee, Good to hear about your research and its use of the design science research (DSR) methods. I am fine with your adapta'on of the 3-cycle model. You have my approval for its use. All the best in your research, Alan

==========

Alan R. Hevner
Citigroup/Hidden River Chair of Distributed Technology
Information Systems and Decision Sciences
College of Business
University of South Florida
4202 East Fowler Ave., CIS1040
Tampa, FL 33620
email: ahevner@usf.edu
office: (813) 9746753
fax: (813) 9746749
cell: (813) 6295540

==========

From: Leanna Woods [mailto:leannaj@utas.edu.au]
Sent: Tuesday, April 4, 2017 8:59 PM
To: Hevner, Alan <AHEVNER@usf.edu>; Hevner, Alan <AHEVNER@usf.edu>
Subject: Request to use Design Science Research Cycles for PhD (Nursing) project: WOODS, Leanna from Australia

Good morning Professor Hevner,

My name is Lee Woods and I am a PhD (Nursing) candidate with the University of Tasmania in Sydney Australia. I am working on the co-design of a mHealth applica'on for heart failure self-management. I believe your three cycle view of design cycle research is the appropriate framework to develop a quality product that is rigorously developed and meets the needs of the end-user. I have adapted the framework to fit our healthcare context. Please find my adaption below:

Appendix C Recruitment posters for Phase I

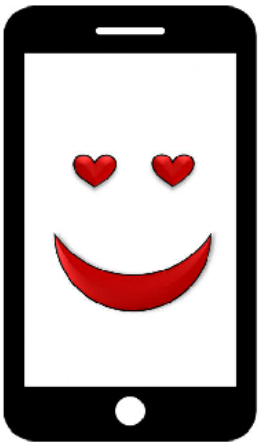
UNIVERSITY of TASMANIA

ST VINCENT'S PRIVATE HOSPITAL SYDNEY

Research participants needed

Help us develop a smartphone app to support patients with heart failure to stay healthy at home.

We need **volunteers** with heart failure and their **carers**.



Talk to us about your health and contribute to St Vincent's research.

Be part of a team of hospital staff, researchers and other patients & carers.

- 9 places left

* Refreshments and car parking provided!

Details

Who? People with heart failure and/or those who care for them. All stages of heart failure, any age. No experience with smartphones required!

How? Share your thoughts & feelings about your health and healthcare.

Who is doing the study? Lee Woods – Clinical Nurse Specialist and PhD student.

Contact

Lee Woods on (02) 8572 7930 or Leanna.Woods@svha.org.au

This study has been approved by the University of Tasmania's Human Research Ethics Committee {H0016365} and St Vincent's Private Hospital Sydney.

Appendix D Participant information and consent form for Phase I

The co-design of a mobile health (mHealth) application to promote self-management in adults with heart failure.

Patient and/or carer co-design

1. Invitation

You are invited to take part in this research project, which is called 'The co-design of a mHealth application to support self-management in adult out-patients with heart failure'. This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

This research is being conducted in partial fulfillment of a Doctor of Philosophy (PhD) degree for the research student, Leanna Woods. Leanna is also a ward nurse at St Vincent's Private Hospital Sydney. Her supervisors are Professor Kim Walker, Dr Jed Duff and Associate Professor Elizabeth Cummings of the University of Tasmania. Kim Walker is the Professor of Healthcare Improvement in the Research Centre at St Vincent's Private Hospital Sydney. This research has been funded by a St Vincent's Clinic Foundation Research Grant.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to the University of Tasmania or other stakeholders. The University of Tasmania or other stakeholders may benefit financially from this research project if, for example, the project assists in any commercial enterprise.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the University of Tasmania, the researchers, their institutions or other stakeholders, there will be no financial benefit to you or your family from these discoveries.

2. What is the purpose of this study?

Managing heart failure at home can improve symptoms and quality of life. Many find managing heart failure confusing, complex and tiring. We believe a well-designed smartphone app (application) could support people with heart failure. Currently we do not know of any application which supports people with heart failure in Australia. We aim to design a smartphone app together in a team of patients, carers and hospital staff. If the

application is well designed and easy to use, in the future other patients with heart failure may benefit from using it.

3. Why have I been invited to participate?

You have been invited because you are an adult with heart failure and a patient at St Vincent's Private Hospital Sydney or St Vincent's Clinic, or you care for an adult with heart failure. Participation in this research is voluntary. If you don't wish to take part, you don't have to. There are no consequences if you decide not to participate and that this will not affect your relationship with the University of Tasmania, St Vincent's Private Hospital Sydney, St Vincent's Clinic, its employees nor the individuals conducting the research.

4. What will I be asked to do?

You will be screened to make sure you are eligible to participate in this research study. You do not need any experience with technologies and you do not need to own a smartphone to participate.

Firstly, you will be asked how you manage heart failure as a patient or carer and provide suggestions how to assist with this management. Together with other patients, their carers, hospital staff, an application developer and the research team, a prototype of the smartphone application will be developed. You will be asked for ongoing feedback to help develop the prototype.
This can be done by participating;

- in up to three (3) group workshops
  AND / OR
- up to six (6) one-on-one conversations with a researcher of 5 to 30-minutes duration with the first conversation lasting about 45 minutes.

The research team will ask your preference.
The duration of the workshops will be two hours and will take place on the St Vincent's Hospital campus. If you prefer, you can contribute to the study by having conversations directly with a researcher at the St Vincent's Hospital Campus. The workshops and the conversations will not be video or audio recorded. The researchers cannot guarantee the confidentiality of participants attending group workshops. They will be spaced apart and be completed by September 2017.

You will also be asked to participate in one interview to tell us about your experience of participating in the research project. This can be done over the phone or in person at the St Vincent's Hospital campus. It will take up to one hour. This interview will be audio taped so that they may be transcribed for analysis. If you would like, you can review and correct the transcript from this interview.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

The number of participants who will be co-designing the app is 12. Hospital staff from St Vincent's Hospital Sydney and St Vincent's Private Hospital Sydney, University of Tasmania researchers and a software developer are also taking part in the design process. This is about 12 more people. After we design the app, we will recruit another 12 participants to evaluate the user-experience of interacting with the app. We expect the study to be completed by February 2018.

5. Are there any possible benefits from participation in this study?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include the use of a version of the smartphone application to assist with the home management of heart failure for other patients in the future.

There are no costs associated with participating in this research project, nor will you be paid. However, you may be reimbursed for any reasonable travel, parking and other expenses associated with research project visits.

6. Are there any possible risks from participation in this study?

The potential risk for participants would be not greater than inconvenience regarding time required to participate in the workshop, conversations and interview.

7. What if I change my mind during or after the study?

If you do consent to participate, you may withdraw at any time and you can do so without providing an explanation. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

8. What will happen to the information when this study is over?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Electronic data will be kept in a password protected computer data and hard copies will be kept in a secure cabinet in the locked office of the Chief Investigator. Only the named investigators will have access to the data. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The personal information that the research team collect and use is information that you tell us from your experience of managing heart failure at home. It is re-identifiable data, that is, we will use a code with your data which is kept separate from the data itself.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

All data will be held for five years from the date of the first publication. Then, hard copies will be deposited in an approved confidential waste receptacle for disposal and electronic data permanently deleted.

9. How will the results of the study be published?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Please let the researcher know if you'd like a copy of Leanna Woods' thesis. We expect this will be around February 2019.

10. What if I have questions about this study?

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Chief Investigator, Professor Kim Walker on 02 8572 7945 or email Kim.Walker@svha.org.au.

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Tasmanian Social Sciences Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, please contact the Executive Officer of the HREC (Tasmania) Network on 03 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. Please quote ethics reference number H0016365.

This information sheet is for you to keep. If you would like to proceed, please review and sign the consent form.

The co-design of a mobile health (mHealth) application to promote self-management in adults with heart failure.

Patient and/or carer co-design

1. I agree to take part in the research study named above.
2. I have read and understood the Information Sheet for this study.
3. The nature and possible effects of the study have been explained to me.
4. I understand that the study involves participation in;
    - up to three (3) group workshops of two-hours duration

    AND / OR

    - up to six (6) one-on-one conversations with a researcher of 5 to 30-minutes duration with the first conversation lasting about 45-minutes

    to be asked how you manage heart failure as a patient or carer and provide suggestions how to assist with this management.

    You will also be asked to participate in a one-hour interview to tell us about your experience of participating in the research project. This interview will be audiotaped.
5. I understand that participation would not be greater than inconvenience regarding time required to participate in the workshop, conversations and interview.
6. I understand that all research data will be securely stored on the locked office of the Chief Investigator at the University of Tasmania premises for five years from the publication of the study results, and will then be destroyed.
7. Any questions that I have asked have been answered to my satisfaction.
8. I understand that the researcher(s) will maintain confidentiality and that any information I supply to the researcher(s) will be used only for the purposes of the research.
9. I understand that the results of the study will be published so that I cannot be identified as a participant.
10. I understand that my participation is voluntary and that I may withdraw at any time without any effect. I understand that I will not be able to withdraw my data after participating in the workshops/conversations as it has been collected anonymously.

See next page.

Participant's name: _____

Participant's signature: _____

Date: _____

Statement by Investigator

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

If the Investigator has not had an opportunity to talk to participants prior to them participating, the following must be ticked.

☐ The participant has received the Information Sheet where my details have been provided so participants have had the opportunity to contact me prior to consenting to participate in this project.

Investigator's name: _____

Investigator's signature: _____

Date: _____

Appendix E Interview questions for Phase I

You are welcome to stop at any time, take a break, or omit answering any number of questions. Do you have any questions for me at this time? When you are ready, we'll start if that's ok?

1. What's your experience with managing your health at home? How do you go with it? Do you get any help?
2. What is your favourite part? Least favourite part? Why?
3. What inconvenience do you experience?
4. What do you need to better manage heart failure at home? How might we support you? How might a mobile app support you?

Closing Remarks:

- Is there anything else you would like to say?
- Do you have any questions?

This is the end of the conversation. Thank-you once again.

*Notes for the interview:

- Ask 'why?' often.
- Find out what's important to them.

<u>Once a storyboard / early version prototype has been developed, request feedback from co-design participants</u>

We've developed a storyboard/early version prototype which we think might improve how people manage their heart failure at home. We'd like to ask your feedback. Please take a look (show the participants, taking time to allow the them to explore it themselves) and let me know what you think of it.

Prompting questions:

- What worked?
- What could be improved?
- What questions do you have?
- What ideas do you have?

Appendix F Research charter

Research charter: The co-design of a mHealth application to promote self-management in adults with heart failure.

Lee (Leanna) Woods, Clinical Nurse Specialist Level 6, St Vincent's Private Hospital Sydney and PhD candidate, University of Tasmania.

T: 02 8572 7930 E: Leanna.Woods@svha.org.au; leannaj@utas.edu.au

Background

Heart failure is a highly prevalent chronic condition and major burden to the Australian healthcare system (1, 2) costing in excess of one billion dollars a year (3). In Australia, up to half of all patients initially hospitalised with heart failure will be re-hospitalised within 3-6 months (3). While optimal adherence to recommended National Heart Foundation of Australia guidelines (4) has positive implications for the patient (lessened symptom burden) (5) and decreased healthcare costs (lessened healthcare usage) (4, 6), adherence is too often suboptimal. In fact, adherence to long-term therapies in chronic disease is only approximately 50% (1) and guideline specific adherence in the heart failure population is also suboptimal (7-9). A mHealth application could help. Initial results support the use of mHealth interventions in the self-management of other chronic conditions.

We believe an appropriately tailored application which encourages and facilitates patient engagement and empowerment in the self-management of their heart failure could improve patient outcomes. We aim to co-design such an application and evaluate the user-experience of the application. As far as we know, this project will be the first mHealth application to specifically support National Heart Foundation of Australia guideline adherence for people with heart failure.

Goals

1. To co-design a mHealth application to promote self-management in adults with heart failure.
2. To evaluate the user experience of the application by adults with heart failure.
3. To interrogate the process of clinicians developing a smartphone app sensitive to their healthcare context.

Project leads

Lee Woods: Project coordinator. This is a student project and makes up part of Lee Woods' Doctor of Philosophy (PhD) degree with the University of Tasmania. Lee's PhD supervisors are Prof Kim Walker, A/Prof Jed Duff and A/Prof Liz Cummings.

Professor Kim Walker: Chief Investigator of the project, Professor of Healthcare Improvement, University of Tasmania and St Vincent's Private Hospital Sydney.

Key stakeholders

Co-investigators: University of Tasmania research supervisors as well as members of the multidisciplinary team who care for patients with heart failure;

- [Name blinded], heart failure nurse practitioner, St Vincent's Hospital Sydney
- [Name blinded], heart failure nurse practitioner, St Vincent's Hospital Sydney
- [Name blinded], physiotherapist, St Vincent's Clinic
- [Name blinded], senior clinical dietitian, St Vincent's Hospital Sydney
- [Name blinded], cardiologist, conjoint professor of medicine, St Vincent's Hospital Sydney and St Vincent's Private Hospital Sydney
- [Name blinded], pharmacist, St Vincent's Private Hospital Sydney
- [Name blinded], cardiac clinical nurse consultant, Cardiac Rehabilitation, St Vincent's Hospital Sydney

Participants: Adults with heart failure and their carers to be recruited from Level 6 and Level 7, St Vincent's Private Hospital Sydney.

App developer: The mHealth application prototype will be synthesised by a professional app developer.

Project milestones

- Ethics approval is requested through the University of Tasmania's Social Sciences HREC and then to the Practice Development and Research Council at St Vincent's Private Hospital Sydney
- Recruit co-design participants
- Three workshops for the purpose of defining the opportunities, ideating a solution and to storyboard a mHealth app prototype
- Engage in ongoing consultations throughout the co-design process for the purpose of providing feedback and refining the prototype in an iterative process
- Process evaluation interviews with co-investigators and participants
- Recruit user-experience participants
- Conduct the user-experience evaluation
- Ongoing, full-time support will be provided by Lee Woods via email, phone and in-person

Timeline

The project will run from March 2017 to March 2018.

Month by month;

Action	M	A	M	J	J	A	S	O	N	D	J	F	M
Co-design participant recruitment	■												
Co-design workshops		■		■		■							
Ongoing consultation with co-investigators and participants		■	■	■	■	■	■						
Process evaluation interviews								■	■				
mHealth application prototype build								■					
User-experience participant recruitment								■					
User-experience evaluation (questionnaire and interview)									■	■	■	■	■

Evaluation

Process evaluation: An interview will be conducted with each participant to understand how the mHealth application was designed in practice compared to how it was planned. The interviews will be audiotaped and qualitatively analysed.

User-experience evaluation: Participants will be asked to interact with the mHealth application prototype for 14 days in the home setting and thereafter report their experience of using the application. The Mobile Application Rating Scale (MARS) (10) together with qualitative interviews will be used to evaluate the application from the perspective of the end-user.

Project budget

The project has been funded by a $25,000 St Vincent's Clinic Foundation Patient-Focused Multidisciplinary Grant to fund professional app development.

In kind support from participating sites is requested to support the conduct of the proposed project. In kind contributions are represented primarily by human resources:

1. Staff attendance at the three workshops and ongoing consultations during the design process
2. Time for staff to participate in process evaluation interviews

Intellectual property

As this is a student project the intellectual property remains with the student, in this case Lee Woods. Project investigators or other stakeholders will not benefit financially from involvement in the research project even if, for example, knowledge acquired from the project proves to be of commercial value.

Investigator role

The investigator role includes;

1. Maintaining and safeguarding the confidentiality of data whether written, electronically recorded or generated or acquired by the team
2. Actively support the team staff members involved in the project

Approval signatures

Signing below provides in principle support for the mHealth for heart failure project at St Vincent's Hospital campus as outlined in this Charter.

Name: _____ Signature:_____

Position: _____ Date:_____

References

1. World Health Organisation. Adherence to long-term therapies : evidence for action. Geneva: World Health Organization; 2003. 198 p.

2. Sahle BW, Owen AJ, Mutowo MP, Krum H, Reid CM. Prevalence of heart failure in Australia: a systematic review. BMC cardiovascular disorders. 2016;16(1):1.

3. National Heart Foundation of Australia. A Systematic Approach to Chronic Heart Failure Care: A Consensus Statement2013. Available from: http://books.google.com.au/books?id=HWB6oAEACAAJ.

4. National Heart Foundation of Australia. Living well with chronic heart failure. . Deakin, A.C.T.: National Heart Foundation of Australia, 2008.; 2008.

5. Driscoll A, Davidson P, Clark R, Huang N, Aho Z. Tailoring consumer resources to enhance self-care in chronic heart failure. Australian Critical Care: Official Journal Of The Confederation Of Australian Critical Care Nurses. 2009;22(3):133-40.

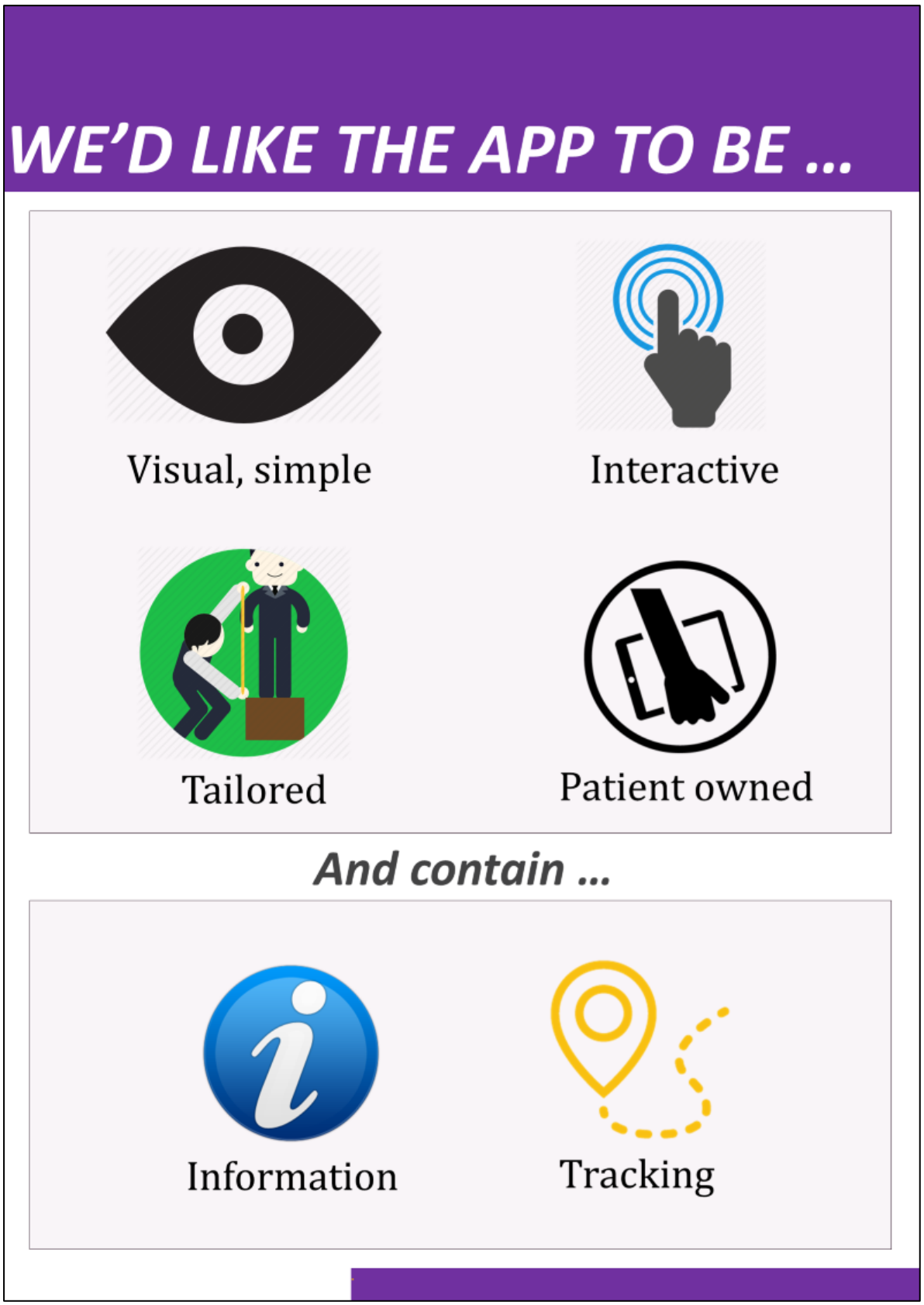
6. Sethares KA, Sosa M-E, Fisher P, Riegel B. Factors Associated With Delay in Seeking Care for Acute Decompensated Heart Failure. Journal of Cardiovascular Nursing. 2014;29(5):429-38.

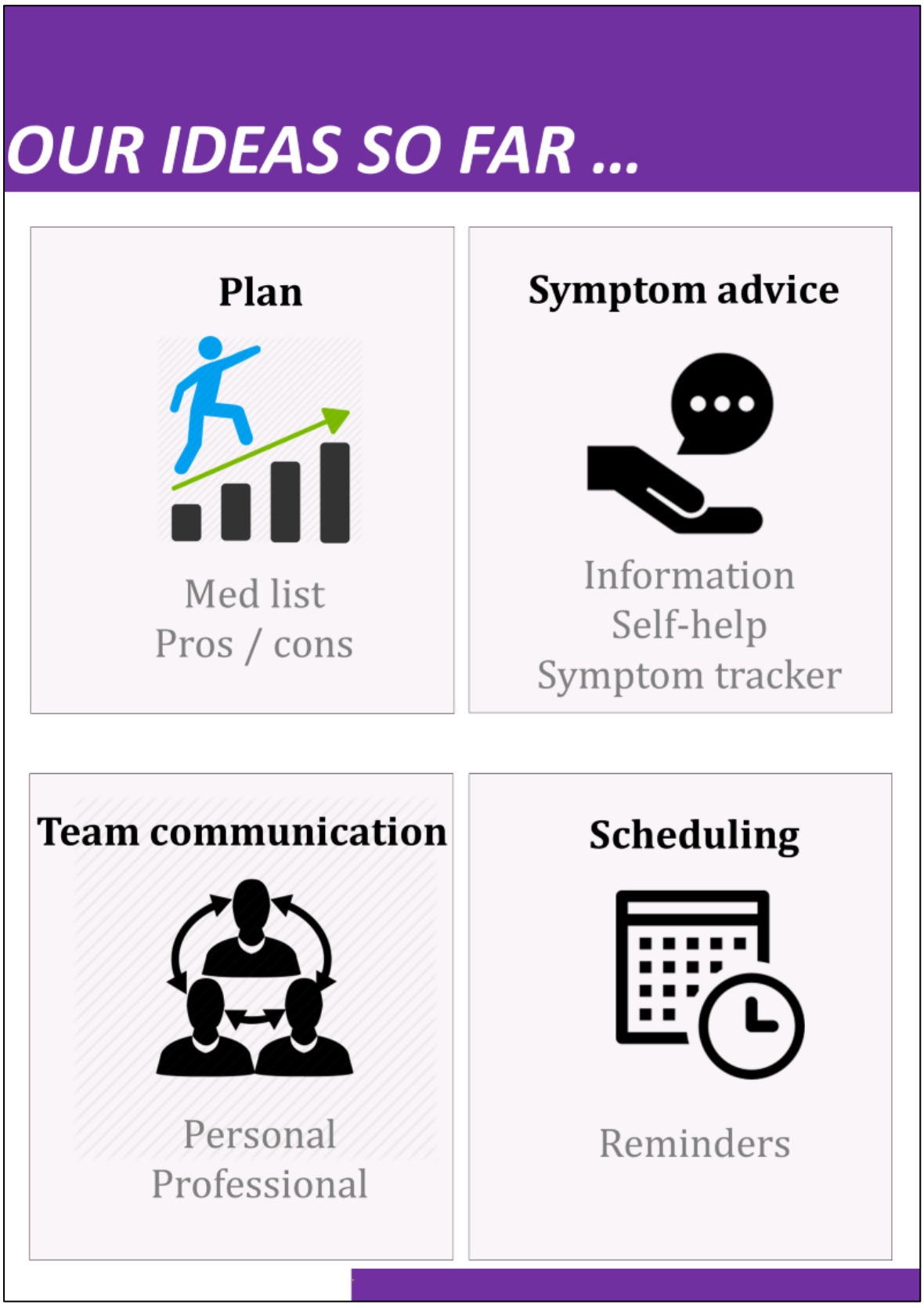
7. van der Wal MHL, Jaarsma T, Moser DK, Veeger NJGM, van Gilst WH, van Veldhuisen DJ. Compliance in heart failure patients: the importance of knowledge and beliefs. European Heart Journal. 2006;27(4):434-40.

8. Dickson VV, Deatrick JA, Riegel B. A typology of heart failure self-care management in non-elders. European Journal Of Cardiovascular Nursing: Journal Of The Working Group On Cardiovascular Nursing Of The European Society Of Cardiology. 2008;7(3):171-81.

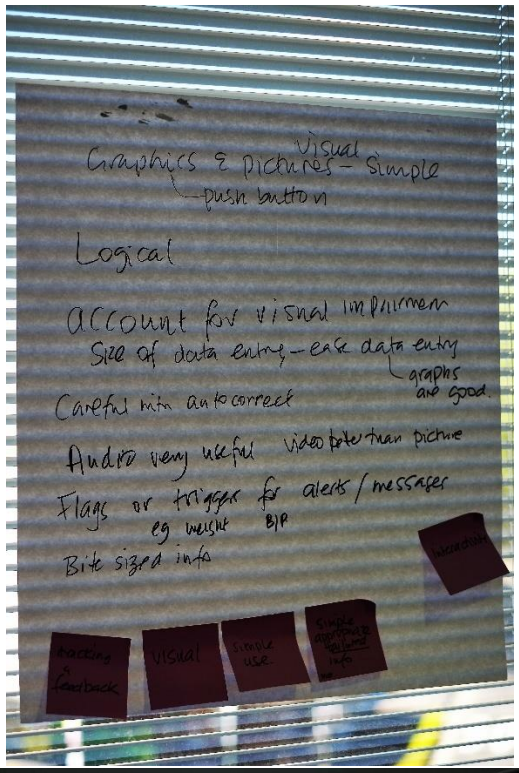
9. Cameron J, Worrall-Carter L, Page K, Stewart S. Self-care behaviours and heart failure: does experience with symptoms really make a difference? European Journal Of Cardiovascular Nursing: Journal Of The Working Group On Cardiovascular Nursing Of The European Society Of Cardiology. 2010;9(2):92-100.

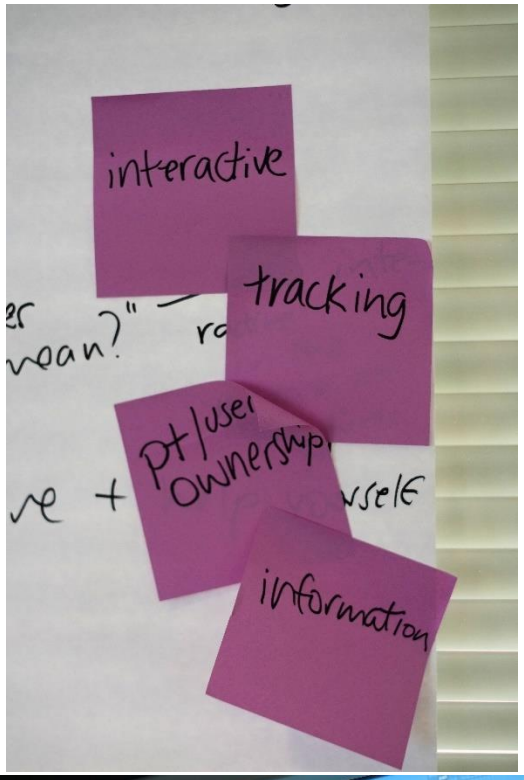
10. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps. JMIR mHealth and uHealth. 2015;3(1):e27.

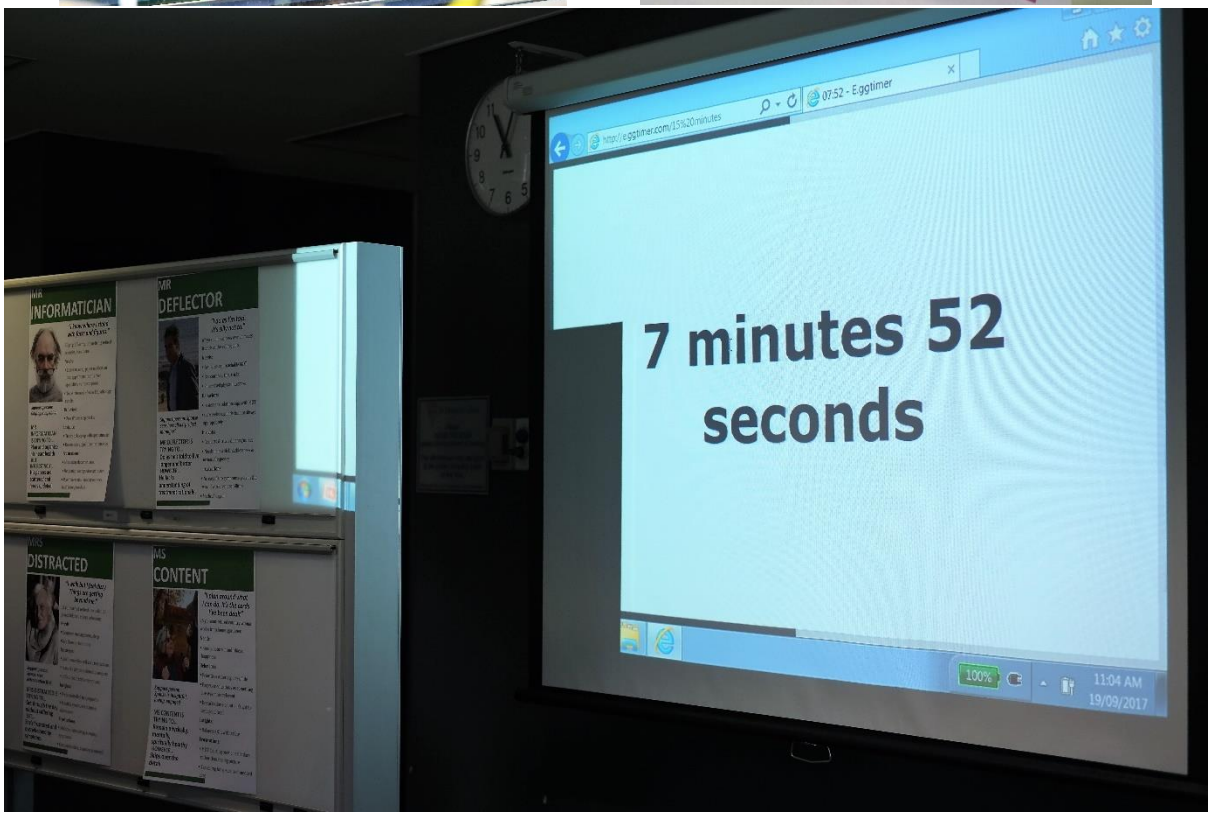

WE'D LIKE THE APP TO BE ...
Visual, simple
Interactive
Tailored
Patient owned
And contain ...
Information
Tracking

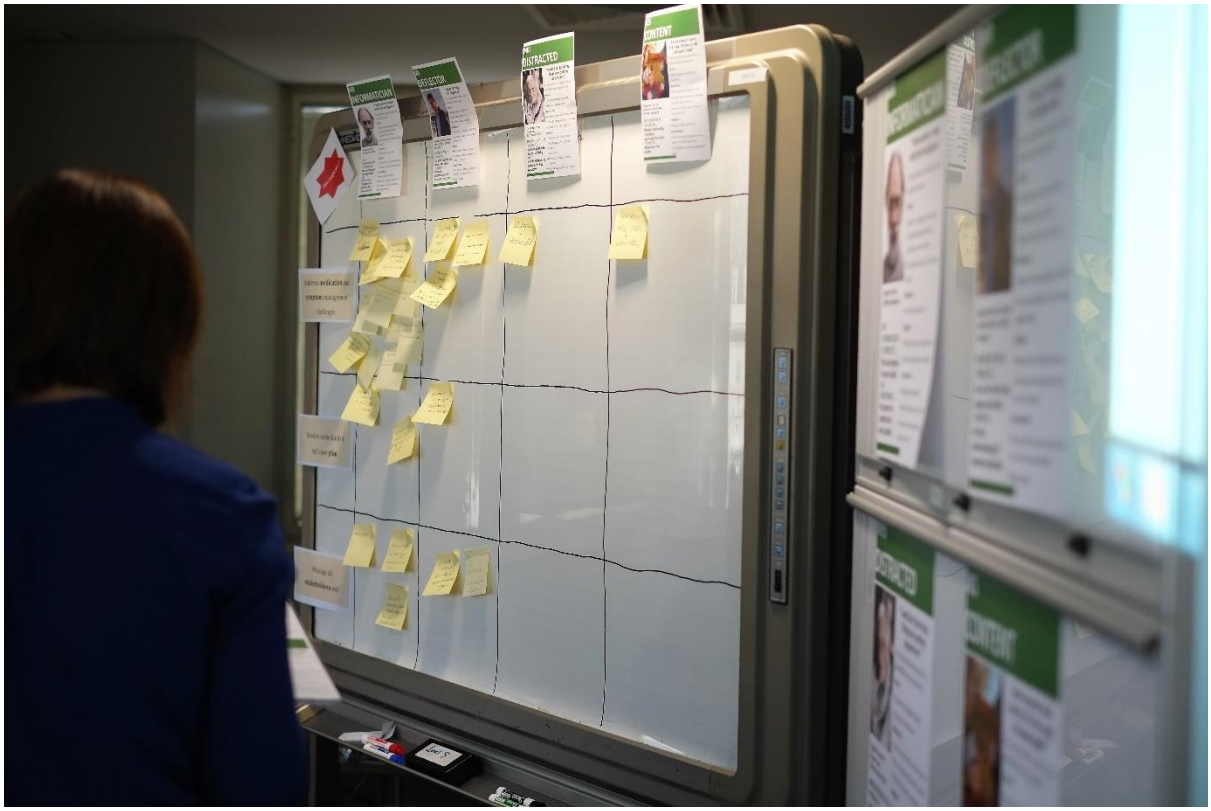

OUR IDEAS SO FAR ...
Plan
Med list
Pros / cons
Symptom advice
Information
Self-help
Symptom tracker
Team communication
Personal
Professional
Scheduling
Reminders

Appendix I Sample photos from workshop 1



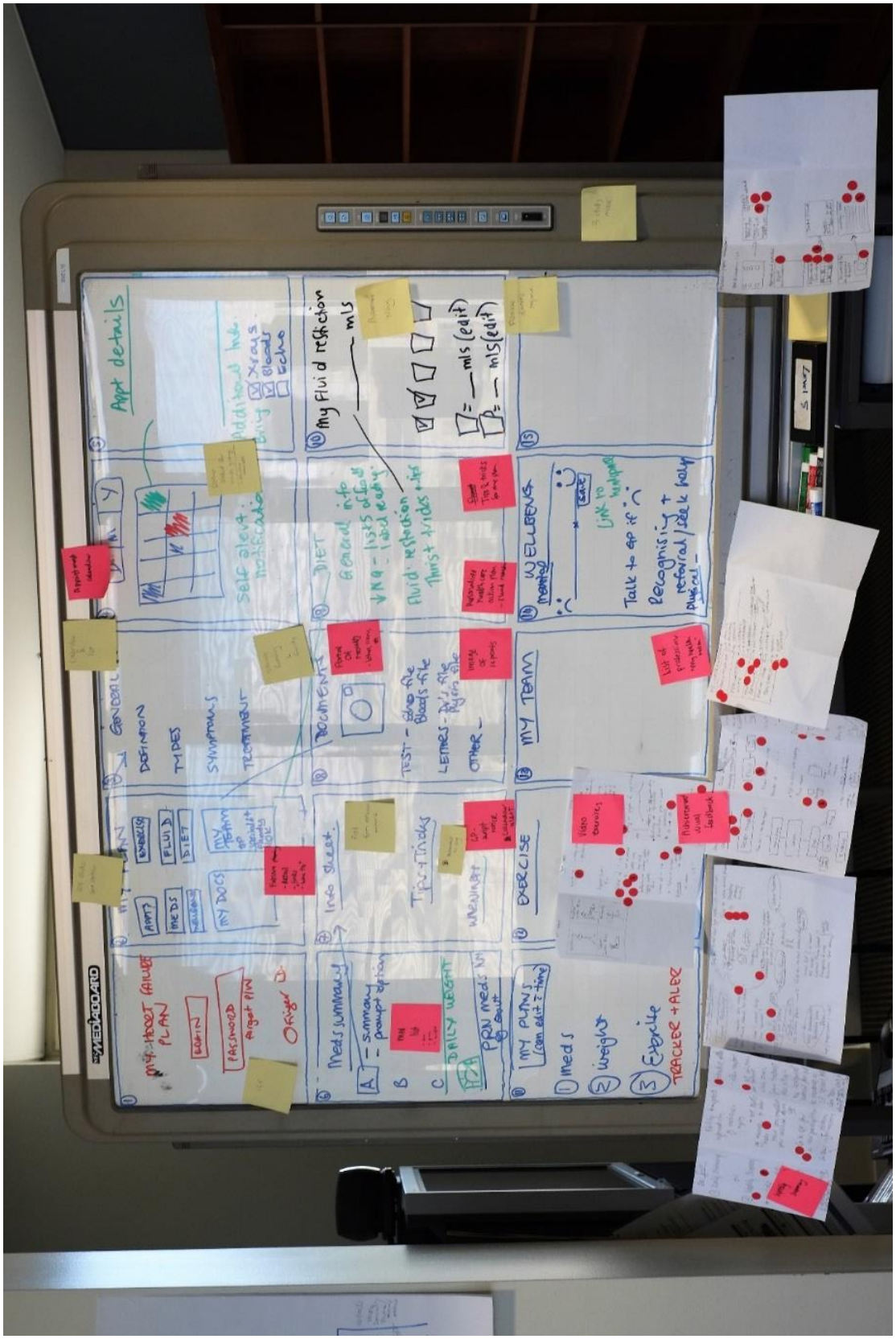




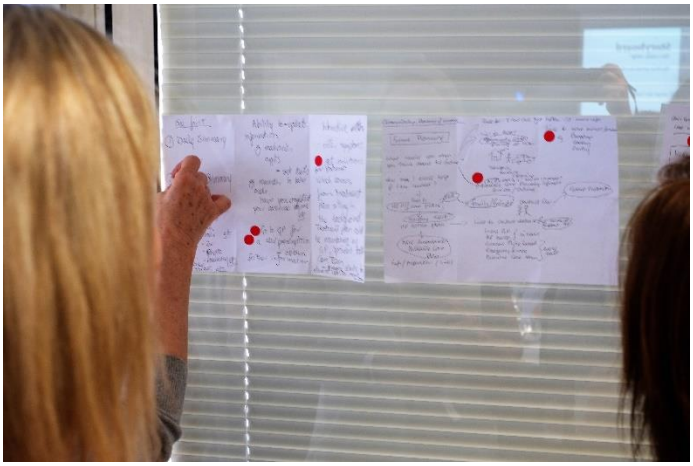



How might we...?
Address medication and symptom management challenges
Involve some kind of self-care plan
Manage all stakeholders well
Interactive Reminder Prompts
Medication list
Link to symptoms
Education tailored to pt
Group Support
Information
Tracker
Reminders
Feedback
Appointment reminder + tracker
Treatment plan
Telehealthy
Family
Diary
Coordination

Appendix J Storyboard



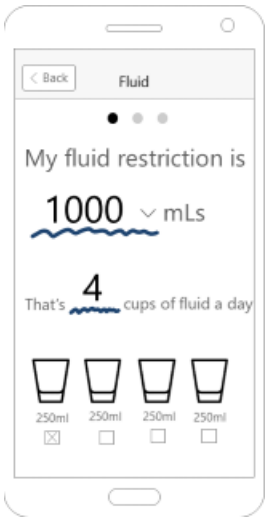
Appendix K Sample photos from workshop 2

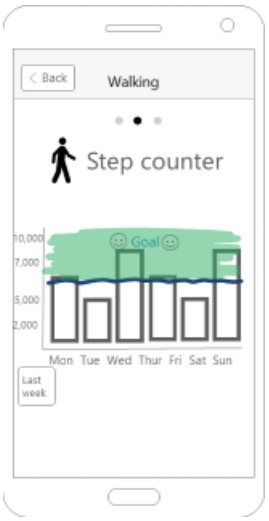


Appendix L Sample PowerMockUp screenshot

Appendix M Initial wireframes

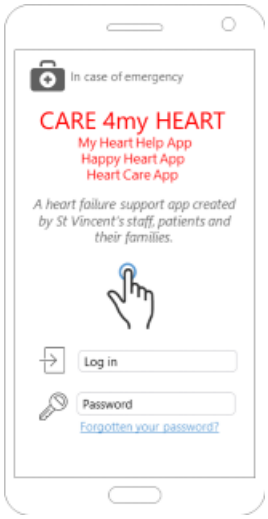
Sample wireframes.

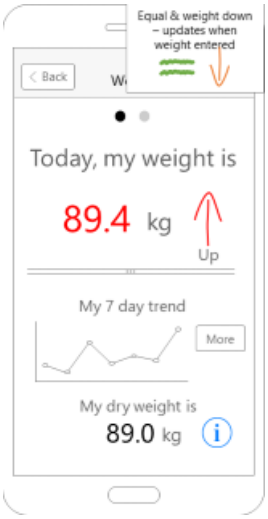


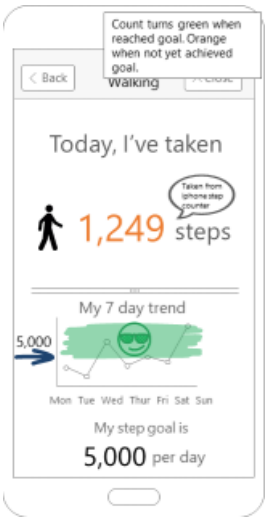


Appendix N Wireframes after the first iteration

Sample wireframes.

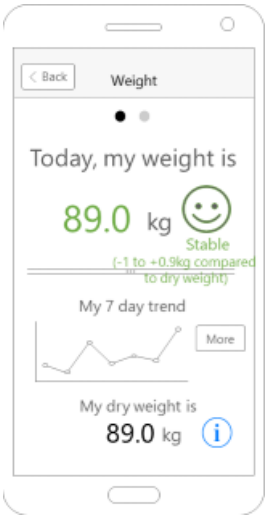


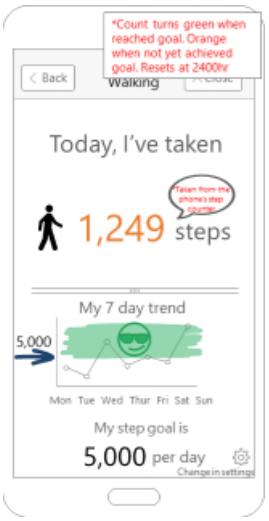




Appendix O Wireframes after the second iteration

Sample wireframes.





Appendix P Sample screenshots from the Trello website

Appendix Q Recruitment posters for Phase III

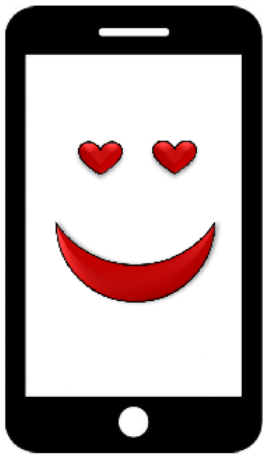
UNIVERSITY of TASMANIA

ST VINCENT'S PRIVATE HOSPITAL SYDNEY

Research participants needed

Patients, family members and St Vincent's staff have developed a smartphone app with the aim to **support people with heart failure**.

We need **volunteers** to review the app.



Contribute to St Vincent's research.

Be part of a team.

- 12 places left

*Refreshments and car parking provided!

Details

Who? People with heart failure who own a smartphone. Android & Apple iOS versions available. All stages of heart failure, any age.

How? Share your thoughts on the app.

Who is doing the study? Lee Woods – Clinical Nurse Specialist and PhD student.

Contact

Lee Woods on (02) 8572 7930 or Leanna.Woods@svha.org.au

This study has been approved by the University of Tasmania's Human Research Ethics Committee {H0016365} and St Vincent's Private Hospital Sydney.

Appendix R Participant information and consent form for Phase III

The co-design of a mobile health (mHealth) application to promote self-management in adult out-patients with heart failure.

User-evaluation

1. Invitation

You are invited to take part in this research project, which is called 'The co-design of a mHealth application to support self-management in adult out-patients with heart failure'. This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

This research is being conducted in partial fulfillment of a Doctor of Philosophy (PhD) degree for the research student, Leanna Woods. Leanna is also a ward nurse at St Vincent's Private Hospital Sydney. Her supervisors are Professor Kim Walker, Dr Jed Duff, Dr Erin Roehrer and Associate Professor Elizabeth Cummings of the University of Tasmania. Kim Walker is the Professor of Healthcare Improvement in the Research Centre at St Vincent's Private Hospital Sydney. This research has been funded by a St Vincent's Clinic Foundation Research Grant.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to the University of Tasmania or other stakeholders. The University of Tasmania or other stakeholders may benefit financially from this research project if, for example, the project assists in any commercial enterprise.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the University of Tasmania, the researchers, their institutions or other stakeholders, there will be no financial benefit to you or your family from these discoveries.

2. What is the purpose of this study?

Managing heart failure at home can improve symptoms and quality of life. Many find managing heart failure confusing, complex and tiring. We believe a well-designed smartphone app (application) could support people with heart failure. Currently we do not

know of any application which supports people with heart failure in Australia. We have designed a smartphone app together in a team of patients, carers and healthcare workers. If the application is well designed and easy to use, in the future other patients with heart failure may benefit from using it.

3. Why have I been invited to participate?

You have been invited because you are an adult with heart failure and a patient of St Vincent's Private Hospital Sydney or St Vincent's Clinic. Participation in this research is voluntary. If you don't wish to take part, you don't have to. There are no consequences if you decide not to participate and that this will not affect your relationship with the University of Tasmania, St Vincent's Private Hospital Sydney, St Vincent's Clinic, its employees nor the individuals conducting the research.

4. What will I be asked to do?

You will be screened to make sure you are eligible to participate in this research study. To participate in this research, you will need to have a smartphone capable of housing the application. The research team will assess this for you. It is preferable to include participants who use a smartphone daily, so that they understand how to use apps.

You will be asked assess the usability of the app for 14 days at home on your own smartphone. You will be asked to interact with the app as long and as frequent as you choose, however we anticipate this would be no more than 20-minutes per day for the 14-day user-experience period equaling 4hrs 40minutes. Then you will be asked for your feedback about the usability of the app. This can be done by completing a questionnaire online or hard copy in a return addressed envelope. The research team will ask your preference.

You will also be asked to participate in one interview to tell us your feedback. This can be done over the phone or in person at the St Vincent's Hospital campus. It will take up to one hour. This interview will be audio taped so that they may be transcribed for analysis. If you would like, you can review and correct the transcript from this interview.

If you chose to participate, continue with your regular care provided by your doctors, nurses and other health professionals. The application does not substitute or add to existing care provided by St Vincent's Private Hospital, your cardiologist and/or nursing staff.

Other patients, carers, healthcare workers from St Vincent's Hospital Sydney and St Vincent's Private Hospital Sydney, University of Tasmania researchers and a software developer took part to design the app. This was about 24 people. We expect the study to be completed by February 2018.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions.

5. Are there any possible benefits from participation in this study?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include the use of a version of the smartphone application to assist with the home management of heart failure for other patients in the future.

There are no costs associated with participating in this research project, nor will you be paid. However, you may be reimbursed for any reasonable travel, parking and other expenses associated with research project visits.

6. Are there any possible risks from participation in this study?

The potential risk for participants would be not greater than inconvenience regarding time required to assess the usability of the app, complete the questionnaire and participate in the interview.

7. What if I change my mind during or after the study?

If you do consent to participate, you may withdraw at any time and you can do so without providing an explanation. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

8. What will happen to the information when this study is over?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Electronic data will be kept in a password protected computer data and hard copies will be kept in a secure cabinet in the locked office of the Chief Investigator. Only the named investigators will have access to the data. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The personal information that the research team collect and use is information that you tell us from assessing the usability of the app. It is re-identifiable data, that is, we will use a code with your data which is kept separate from the data itself.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

All data will be held for five years from the date of the first publication. Then, hard copies will be deposited in an approved confidential waste receptacle for disposal and electronic data permanently deleted.

9. How will the results of the study be published?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Please let the researcher know if you'd like a copy of Leanna Woods' thesis. We expect this will be around February 2019.

10. What if I have questions about this study?

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Chief Investigator, Professor Kim Walker on 04 or email kim.walker@utas.edu.au.

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Tasmanian Social Sciences Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, please contact the Executive Officer of the HREC (Tasmania) Network on 03 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. Please quote ethics reference number H0016365.

This information sheet is for you to keep. If you would like to proceed, please review and sign the consent form.

The co-design of a mobile health (mHealth) application to promote self-management in adults with heart failure.

User-experience

1. I agree to take part in the research study named above.
2. I have read and understood the Information Sheet for this study.
3. The nature and possible effects of the study have been explained to me.
4. I understand that the study involves being asked to assess the usability of a new smartphone app for 14 days at home on my own smartphone, up to 20-minutes per day. Then I will be asked for my feedback about the usability of the app via a questionnaire and one-hour interview. This interview will be audiotaped.
5. I understand that participation would be not greater than inconvenience regarding time required to assess the usability of the app, complete the questionnaire and participate in the interview.
6. I understand that all research data will be securely stored on the locked office of the Chief Investigator at the University of Tasmania premises for five years from the publication of the study results, and will then be destroyed.
7. Any questions that I have asked have been answered to my satisfaction.
8. I understand that the researcher(s) will maintain confidentiality and that any information I supply to the researcher(s) will be used only for the purposes of the research.
9. I understand that the results of the study will be published so that I cannot be identified as a participant.
10. I understand that my participation is voluntary and that I may withdraw at any time without any effect. I understand that I will not be able to withdraw my data after participating as it has been collected anonymously.

See next page.

Participant's name: _____

Participant's signature: _____

Date: _____

Statement by Investigator

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

If the Investigator has not had an opportunity to talk to participants prior to them participating, the following must be ticked.

☐ The participant has received the Information Sheet where my details have been provided so participants have had the opportunity to contact me prior to consenting to participate in this project.

Investigator's name: _____

Investigator's signature: _____

Date: _____

Appendix S Modified Mobile Application Rating Scale

Thank you for taking the time to participate in this research and complete this questionnaire. All items are rated on a 5-point scale from "1. Inadequate" to "5. Excellent". Please circle the number that most accurately represents the quality of the app component you are rating. Please use the descriptors provided for each response category.

SECTION A – ENGAGEMENT

1. Entertainment: Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?

1 Dull, not fun or entertaining at all

2 Mostly boring

3 OK, fun enough to entertain user for a brief time (< 5 minutes)

4 Moderately fun and entertaining, would entertain user for some time (5-10 minutes total)

5 Highly entertaining and fun, would stimulate repeat use

2. Interest: Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?

1 Not interesting at all

2 Mostly uninteresting

3 OK, neither interesting nor uninteresting; would engage user for a brief time (< 5 minutes)

4 Moderately interesting; would engage user for some time (5-10 minutes total)

5 Very interesting, would engage user in repeat use

3. Customisation: Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?

1 Does not allow any customisation or requires setting to be input every time

2 Allows insufficient customisation limiting functions

3 Allows basic customisation to function adequately

4 Allows numerous options for customisation

5 Allows complete tailoring to the individual's characteristics/preferences, retains all settings

4. Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Please note: these functions need to be customisable and not overwhelming in order to be perfect.

1 No interactive features and/or no response to user interaction

2 Insufficient interactivity, or feedback, or user input options, limiting functions

3 Basic interactive features to function adequately

4 Offers a variety of interactive features/feedback/user input options

5 Very high level of responsiveness through interactive features/feedback/user input options

5. Target group: Is the app content (visual information, language, design) appropriate for the target audience?

1 Completely inappropriate/unclear/confusing

2 Mostly inappropriate/unclear/confusing

3 Acceptable but not targeted. May be inappropriate/unclear/confusing

4 Well-targeted, with negligible issues

5 Perfectly targeted, no issues found

Office use only
A. Engagement mean score =

SECTION B - FUNCTIONALITY

6. Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?

1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)

2 Some functions work, but lagging or contains major technical problems

3 App works overall. Some technical problems need fixing/Slow at times

4 Mostly functional with minor/negligible problems

5 Perfect/timely response; no technical bugs found/contains a 'loading time left' indicator

7. Ease of use: How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?

1 No/limited instructions; menu labels/icons are confusing; complicated

2 Useable after a lot of time/effort

3 Useable after some time/effort

4 Easy to learn how to use the app (or has clear instructions)

5 Able to use app immediately; intuitive; simple

8. Navigation: Is moving between screens logical/accurate/appropriate/uninterrupted; are all necessary screen links present?

1 Different sections within the app seem logically disconnected and random/confusing/navigation is difficult

2 Usable after a lot of time/effort

3 Usable after some time/effort

4 Easy to use or missing a negligible link

5 Perfectly logical, easy, clear and intuitive screen flow throughout, or offers shortcuts

9. Gestural design: Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?

1 Completely inconsistent/confusing

2 Often inconsistent/confusing

3 OK with some inconsistencies/confusing elements

4 Mostly consistent/intuitive with negligible problems

5 Perfectly consistent and intuitive

Office use only
B. Functionality mean score =

SECTION C - AESTHETICS

10. Layout: Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?

1 Very bad design, cluttered, some options impossible to select/locate/see/read device display not optimised

2 Bad design, random, unclear, some options difficult to select/locate/see/read

3 Satisfactory, few problems with selecting/locating/seeing/reading items or with minor screensize problems

4 Mostly clear, able to select/locate/see/read items

5 Professional, simple, clear, orderly, logically organised, device display optimised. Every design component has a purpose

11. Graphics: How high is the quality/resolution of graphics used for buttons/icons/menus/content?

1 Graphics appear amateur, very poor visual design - disproportionate, completely stylistically inconsistent

2 Low quality/low resolution graphics; low quality visual design – disproportionate, stylistically inconsistent

3 Moderate quality graphics and visual design (generally consistent in style)

4 High quality/resolution graphics and visual design – mostly proportionate, stylistically consistent

5 Very high quality/resolution graphics and visual design - proportionate, stylistically consistent throughout

12. Visual appeal: How good does the app look?

1 No visual appeal, unpleasant to look at, poorly designed, clashing/mismatched colours

2 Little visual appeal – poorly designed, bad use of colour, visually boring

3 Some visual appeal – average, neither pleasant, nor unpleasant

4 High level of visual appeal – seamless graphics – consistent and professionally designed

5 As above + very attractive, memorable, stands out; use of colour enhances app features/menus

Office use only
C. Aesthetics mean score =

SECTION D - INFORMATION

13. Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?

N/A	There is no information within the app
1	Irrelevant/inappropriate/incoherent/incorrect
2	Poor. Barely relevant/appropriate/coherent/may be incorrect
3	Moderately relevant/appropriate/coherent/and appears correct
4	Relevant/appropriate/coherent/correct
5	Highly relevant, appropriate, coherent, and correct

14. Quantity of information: Is the extent coverage within the scope of the app; and comprehensive but concise?

N/A	There is no information within the app
1	Minimal or overwhelming
2	Insufficient or possibly overwhelming
3	OK but not comprehensive or concise
4	Offers a broad range of information, has some gaps or unnecessary detail; or has no links to more information and resources
5	Comprehensive and concise; contains links to more information and resources

15. Visual information: Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?

N/A	There is no visual information within the app (e.g. it only contains audio, or text)
1	Completely unclear/confusing/wrong or necessary but missing
2	Mostly unclear/confusing/wrong
3	OK but often unclear/confusing/wrong
4	Mostly clear/logical/correct with negligible issues
5	Perfectly clear/logical/correct

Office use only
D. Information mean score * =
**** Exclude questions rated as "N/A" from the mean score calculation.***

SECTION E – QUALITY

16. Would you recommend this app to people who might benefit from it?

1	Not at all	I would not recommend this app to anyone
2		There are very few people I would recommend this app to
3	Maybe	There are several people whom I would recommend it to
4		There are many people I would recommend this app to
5	Definitely	I would recommend this app to everyone

17. How many times do you think you would use this app in the next 12 months if it was relevant to you?

1	None
2	1-2
3	3-10
4	10-50
5	>50

18. Would you pay for this app?

1	No
3	Maybe
5	Yes

19. What is your overall star rating of the app?

1	★	One of the worst apps I've used
2	★★	
3	★★★	Average
4	★★★★	
5	★★★★★	One of the best apps I've used

Office use only
Scoring App quality scores for SECTION
A: Engagement Mean Score =
B: Functionality Mean Score =
C: Aesthetics Mean Score =
D: Information Mean Score =
App quality mean Score =
App subjective quality Score =

SECTION F – APP SPECIFIC

20. Awareness: This app is likely to increase my awareness of the importance of addressing heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

21. Knowledge: This app is likely to increase my knowledge/understanding of heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

22. Attitudes: This app is likely to change my attitude toward improving heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

23. Intention to change: This app is likely to increase my intentions/motivation to address heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

24. Help seeking: Use of this app is likely to encourage further help seeking for my heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

25. Behaviour change: Use of this app is likely increase/decrease my heart failure self-care

1 Strongly disagree

2

3

4

5 Strongly Agree

Appendix T Interview schedule for Phase III

Aim: To allow participants the opportunity to comment on their user-experience generally and to capture qualitative information about the perceived effect that the app could have on heart failure self-care. No clinical data will be collected and no health outcomes will be measured.

Interview details:

Thank you for taking the time to participate in this research and for completing the questionnaire. In this interview, I'd like to ask you your experience of interacting with the application interface. We really appreciate you taking the time to use the app and share your thoughts about it. Before we start, do you have any questions for me at this time? When you are ready, I'll start the audiotape if that's ok?

- What was your overall experience of interacting with the application interface?
- What worked well?
- What could be improved?

Ask participants to explain their Likert Scale responses in section F (App specific questions) which includes the following questions: Are you likely to;

- increase **awareness** of the importance of heart failure self-care? Why?
- increase **knowledge** about heart failure self-care? Why?
- change **attitudes** towards improving heart failure self-care? Why?
- increase **motivation** to address heart failure self-care? Why?
- encourage further **help seeking** for heart failure self-care? Why?
- **increase/decrease** heart failure self-care? Why?

Note: *Self-care* is a term often more familiar to patients than self-management. Where possible we will use the phrase; *manage your heart failure at home*.

Appendix U Ethical approval letter from the University of Tasmania

Social Science Ethics Officer
Private Bag 01 Hobart
Tasmania 7001 Australia
Tel: (03) 6226 2763
Fax: (03) 6226 7148
Katherine.Shaw@utas.edu.au

HUMAN RESEARCH ETHICS COMMITTEE (TASMANIA) NETWORK

03 April 2017

Professor Kim Walker
School of Health Sciences
University of Tasmania

Student Researcher: Leanna Woods

Sent via email

Dear Professor Walker

Re: MINIMAL RISK ETHICS APPLICATION APPROVAL
Ethics Ref: **H0016365 - The co-design of a mobile health (mHealth) application to promote self-management in adults with heart failure**

We are pleased to advise that acting on a mandate from the Tasmania Social Sciences HREC, the Chair of the committee considered and approved the above project on 31 March 2017.

This approval constitutes ethical clearance by the Tasmania Social Sciences Human Research Ethics Committee. The decision and authority to commence the associated research may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or review by your research governance coordinator or Head of Department. It is your responsibility to find out if the approval of other bodies or authorities is required. It is recommended that the proposed research should not commence until you have satisfied these requirements.

Please note that this approval is for four years and is conditional upon receipt of an annual Progress Report. Ethics approval for this project will lapse if a Progress Report is not submitted.

The following conditions apply to this approval. Failure to abide by these conditions may result in suspension or discontinuation of approval.

1. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval, to ensure the project is conducted as approved by the Ethics Committee, and to notify the Committee if any investigators are added to, or cease involvement with, the project.

2. Complaints: If any complaints are received or ethical issues arise during the course of the project, investigators should advise the Executive Officer of the Ethics Committee on 03 6226 7479 or human.ethics@utas.edu.au.

3. Incidents or adverse effects: Investigators should notify the Ethics Committee immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.

4. Amendments to Project: Modifications to the project must not proceed until approval is obtained from the Ethics Committee. Please submit an Amendment Form (available on our website) to notify the Ethics Committee of the proposed modifications.

5. Annual Report: Continued approval for this project is dependent on the submission of a Progress Report by the anniversary date of your approval. You will be sent a courtesy reminder closer to this date. **Failure to submit a Progress Report will mean that ethics approval for this project will lapse.**

6. Final Report: A Final Report and a copy of any published material arising from the project, either in full or abstract, must be provided at the end of the project.

Yours sincerely

Katherine Shaw
Executive Officer
Tasmania Social Sciences HREC

Appendix V Ethical approval letter from St Vincent's Private Hospital Sydney

ST VINCENT'S
PRIVATE HOSPITAL
CONDUCTED BY THE SISTERS OF CHARITY OF AUSTRALIA

MAGNET RECOGNIZED
AMERICAN NURSES CREDENTIALING CENTER

10th April 2017

Leanna Woods
SVPHS UTAS Research Office
106 Boundary St Paddington 2021

Dear Mrs Woods,

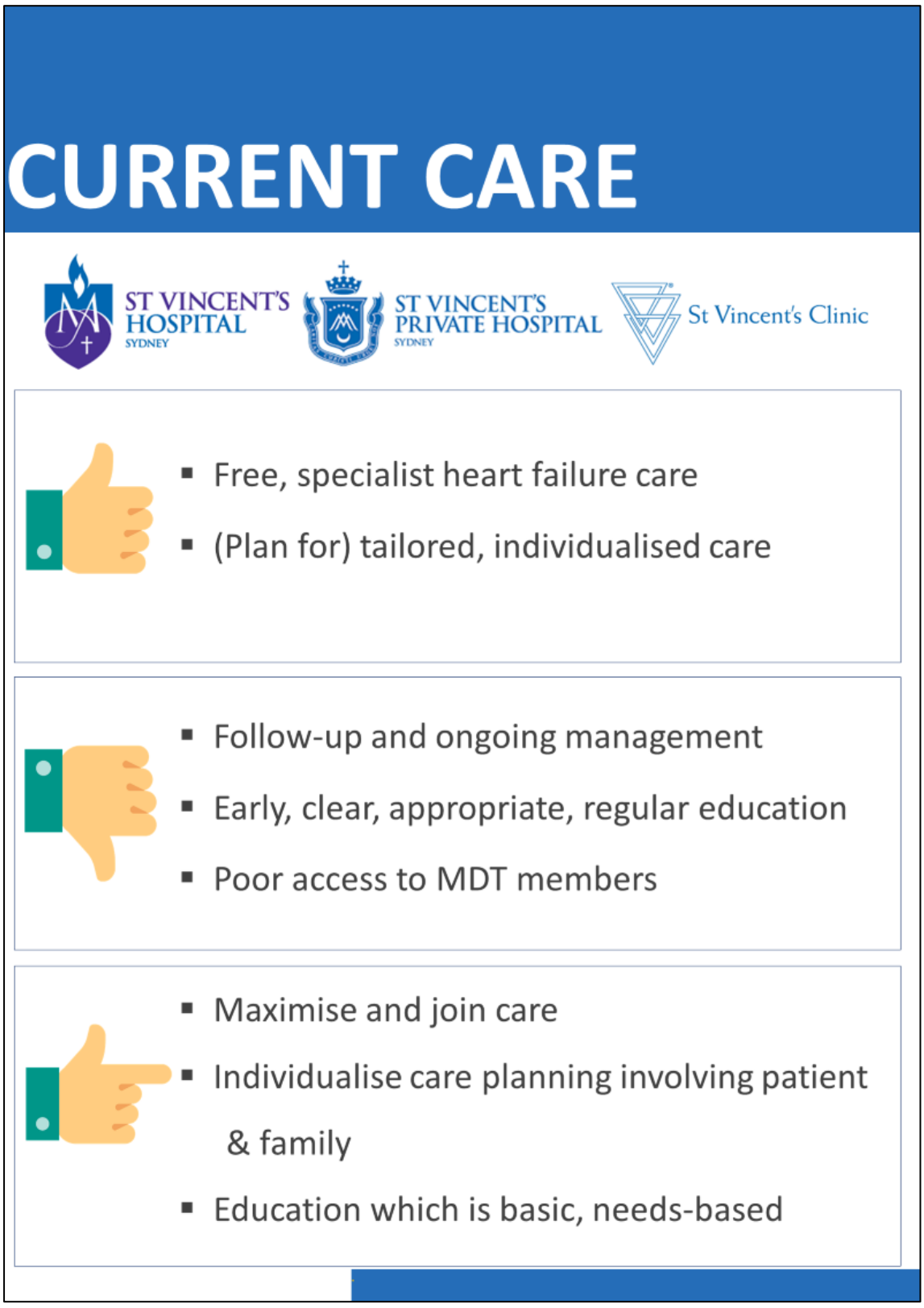
Re: Research project ethics application outcome

I write to inform you that your protocol entitled: The co-design of a mobile health (mHealth) application to promote self-management in adults with heart failure has been defined as 'low risk' and is therefore exempt from full HREC review and has been approved by the SVPH Practice Development & Research Council.

On completion of the study could you please forward to my office a copy of the final report/draft manuscript for publication for our files please.

Edel Murray
Quality Manager
Edel.murray@svha.org.au

Appendix W Current care summary



Appendix X Achievements related to this thesis

Scholarships

- Research Training Program (RTP), full-time stipend for 3.25 years
- The District Nurses Elite Research Scholarship, stipend for 3.25 years
- Bursary from EIT Health (European Institute of Innovation and Technology) to attend the Summer School on User-centred Design of eHealth and mHealth Systems in Dublin and Stockholm

Grants

- St Vincent's Clinic Foundation Multidisciplinary Patient-Focused Grant
- University of Tasmania School of Health Sciences Research Top up Grant
- University of Tasmania's HDR Conference and Research Travel Scheme
- University of Tasmania's School of Health Sciences research travel funding
- St Vincent's Clinic Foundation Conference Presentation Grant X2
- Sigma Theta Tau Honor Society of Nursing Conference Grant

Awards

- St Vincent's Clinic Foundation Clinical Excellence Award in Nursing
- Sigma Theta Tau Honor Society of Nursing Chapter's Post Graduate Research Student Award
- Finalist, Australian Society for Medical Research (ASMR) Postgraduate Research Student Award
- Finalist, Health Informatics Society of Australia (HISA) 'Branko Cesnik' best student paper award

Conference Presentations

- Health Informatics Conference, Melbourne Convention and Exhibition Centre, South Wharf, VIC, 2019 (upcoming)
- Nursing Informatics Australia Conference, Melbourne Convention and Exhibition Centre, South Wharf, VIC, 2019 (upcoming)
- Health Informatics Conference, International Convention Centre, Darling Harbour, NSW, 2018
- Australian Telehealth Conference, Novotel Sydney Central, NSW, 2018
- Australian Conference on Human Computer Interaction, Queensland University of Technology, Brisbane, QLD, 2017
- Context Sensitive Health Informatics Conference, City University of Hong Kong, Hong Kong, 2017

End of thesis.